EVALUATION OF A DENTAL AMALGAM ALLOY CONTAINING THE FLUORIDE ADDITIVE STANNOUS HEXAFLUOROZIRCONATE

by

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Submitted to the Faculty of the Graduate School in partial fulfillment of the requirements for the degree of Master of Science in Dentistry, Indiana University - Purdue University, at Indianapolis, School of Dentistry, 1973.

ACKNOWLEDGMENTS

A combined laboratory and clinical study requires the input and efforts of many people, of whom each should be willing to accept his fair share of the responsibility for the end-product. To this end, those who should be held accountable are acknowledged below: (no implication is intended by order of reference.)

Gunnar Ryge - who introduced me to the science of dental materials, particularly the area of clinical research.

The Division of Dental Health, Bureau of Health Resources Development, HRA, DHEW - who had enough confidence to support my graduate training.

Ralph W. Phillips - who, upon hearing of my past clinical episodes, felt I could do it right this time.

Marjorie L. Swartz - who, with patience and understanding guided me through the laboratory phase of the study.

Rita Mehra - who participated as a clinical examiner and kept the results unbiased.

Barbara Rhodes, Hazel Clark, and Ray Pierce - who performed the fluoride studies and tolerated my laboratory activities and questions.

S. William Brewer, Superintendent, Soldiers' and Sailors' Children's Home, Knightstown, Indiana - who provided the cooperation and support necessary for a successful clinical study.

The participating children - who make pedodontics a joy.

Judy McCullough - who assisted me most capably chairside and kept complete clinical records.

Richard Scott - who produced the thesis illustrations.

Lee Gardner - who, after deciphering my notes and scratchings, typed and compiled them into a thesis.

And last, a special note for James Roche, a dental educator whose concern goes beyond technical and cognitive skills and includes the affective domain through personal example, all to instill within the student the capabilities and desire to provide the best care for the child.

R. G. W.

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

TABLES AND FIGURES

INTRODUCTION

The rationale for adding fluoride compounds to dental amalgam alloys is based on studies [1,2,3] which indicate that fluoride released from silicate cement restorations is taken up by the surrounding enamel, reducing its solubility. As a result, the enamel is more resistant to acid attack and silicate restorations show less susceptibility to recurrent caries [1,4,5,6] than other restorative materials.

Recurrent caries is closely associated with amalgam failures. [7,8,9] It is conceivable that the inclusion of a fluoride compound in the dental alloy could provide a source of fluoride ions to reduce enamel solubility at the margins of the restoration, thereby reducing the possibility of recurrent caries.

In laboratory studies, adding fluoride compounds to dental alloys has increased the fluoride content of the tooth structure adjacent to the restoration and has reduced enamel solubility. [10,11] The required concentration of fluoride slightly reduced the strength properties of the alloys, but the alloys still met the physical requirements of ADA specification #1. [10-15]

Recently a joint project between the L.D. Caulk Co. and the Departments of Dental Materials and Oral Health Research, I.U.P.U.I. School of Dentistry, has led to the development of a dental amalgam alloy containing the fluoride compound stannous hexafluorozirconate, at a concentration of 0.5% by weight. Stannous hexafluorozirconate was chosen as the fluoride additive since in vitro and in vivo studies have shown that the effectiveness of this agent may be significantly greater than stannous fluoride. [16,17,18]

Though the reports of fluoride compounds added to dental alloys indicate that, at 0.5% by weight, fluoride compounds should be of no detriment to the properties of the alloy and that fluoride is released from amalgam, no such data are available to support the use of stannous hexafluorozirconate as a fluoride additive.

Any new additive must be evaluated. The fluoride may be present in a stable form and not released; or the released fluoride may react with other products and not be available for uptake. The rate and duration of fluoride release can vary for different fluoride compounds, making some of greater potential than others. The fluoride additive may have a tendency to aggregate in large particles which could adversely affect the properties of the alloy. Also the dissolution of the fluoride could alter the surface microstructure of the amalgam, rendering it more subject to corrosion. In addition, since data are lacking concerning the clinical behavior of fluoride-containing alloys, studies evaluating the clinical effect of fluoride additives are needed, not only to determine the physical behavior of the fluoride containing amalgam, but also the efficacy of adding fluoride to dental alloys. Only then is it possible to determine whether the claimed laboratory properties have clinical significance that will benefit the patient.

This present study was designed to evaluate the stannous hexafluorozirconate-containing alloy clinically and in the laboratory. The purpose was to determine how the fluoride compound might affect the physical properties of the alloy,

the clinical behavior of the amalgam restoration, and its ability to prevent or inhibit new caries at the margins of the restorations.

REVIEW OF THE LITERATURE

Prevalence of Recurrent Caries

If operative dentistry is to be considered preventive as well as restorative, then preventing recurrent caries is as important as treating primary caries. Recurrent caries about amalgam restorations is a recognized problem, but attempts to determine its magnitude have produced a wide range of results. Harvey[19] found a low recurrent caries prevalence of 6.2% in a population of patients who had received care at a dental school. The amalgam restorations were from two to nine years old. Seino[20] reported a high recurrent caries prevalence of 36.5%. This occurred in a population of school children. The amalgam restorations were two to five years old. Differential data between primary and permanent teeth were not indicated in the report.

Other studies do little to narrow this range or more adequately indicate a possible prevalence of recurrent caries. Records[21] from the Great Lakes Naval Training Station in Illinois show that about 12% of the amalgam restorations examined had to be replaced because of recurrent caries. Nineteen percent of the five year or older amalgam restorations observed by Baumgartner[22] had recurrent caries. Laswell,[23] examining 17 to 20-year-old naval recruits, found that 9.2% of the surfaces restored with amalgam had recurrent caries. This ranged from 8.2% of the occlusal surfaces on mandibular second molars to 12.2% of maxillary second molars. His results also indicated that, although proximal surfaces are less than one-half as likely to decay initially as the occlusal surface, they are equally susceptible to recurrent caries. The 12 and 13-year-old children examined by Broad-

hurst[24] showed a higher prevalence. Close to 23% of the amalgam-restored occlusal surfaces of first permanent molars had recurrent caries; 26% of the occlusal restorations in second molars had recurrent caries. Proximal margins of 30% of the Class II amalgam restorations in first molars showed signs of recurrent caries; this was 18% in second molars.

This wide range of prevalence findings can best be explained by the fact that distinctly different populations were sampled. Also, no specific criteria for caries evaluation were common to all surveys reported; nor were the skills and judgments of the various examiners calibrated. But the overall prevalence findings do indicate that recurrent caries about amalgam restorations is a critical problem.

Causes of Recurrent Caries

Before solutions to a problem can be proposed, it is necessary to have some understanding as to the cause. A review of many articles concerning amalgam failures and recurrent caries indicates that there are four areas to be considered in evaluating causes for recurrent caries: the dental material, the friable enamel cavosurface margin, the dental operator, and the patient's oral environment.

1. The Dental Material

Marginal Fracture

Amalgam restorations show a very high frequency of marginal fracture, to the point that this clinical behavior is considered an inherent characteristic and weakness of the amalgam itself. The cause of this marginal fracture or disintegration is not

fully understood, though several explanations have been proposed, based on the physical properties of amalgam.

Amalgam is a brittle material and it has a low modulus of resilience. Therefore, in areas of less volume, as the marginal areas of the amalgam restoration, impact energy is likely to cause chipping and fracture. Mahler[25] also refers to amalgam having a low bending strength or modulus of rupture. Fracture in bending propagates from regions of maximum tensile stress. Amalgam, being a brittle material, is weak under tensile stress. The elastic properties of the supporting tooth structure allows for bending of the amalgam, which results in marginal fractures. These properties of low resilience and bending strength make up what has been vaguely referred to as the poor "edge strength" of amalgam restorations.

Mahler et al[26,27,28] feel that there may be a relationship between marginal fracture and the flow properties of amalgam. They have demonstrated marginal extrusion both in the laboratory[26] and clinically.[27] Extruded and therefore unsupported amalgam margins would be most susceptible to fracture. These authors also have shown that laboratory tests for dynamic creep, static creep, and slow compression strength appear to predict clinical marginal failure.[28]

Jorgensen[29] has suggested that electrolytic corrosion at the cavo-surface margin and along the amalgam-tooth interface is the cause for marginal fracture. The corrosion causes a release of mercury which diffuses into the marginal amalgam, causing it to expand and deflect away from the cavity wall. This mercuroscopic expansion leaves the amalgam unsupported and subject to fracture.

The clinical significance of marginal breakdown is not known, though clinicians prefer margins that show little or no deterioration. Nadal[30] has reported that marginal deterioration appears to occur at a relatively constant rate up to approximately 15 months. Thereafter, new marginal fractures decrease, with no apparent worsening in areas of previous fracture. Other studies confirm this trend of marginal deterioration.[31-34] In these studies ranging in duration from 24-36 months, no recurrent caries was reported. Jorgensen[35] has demonstrated microscopic evidence of recurrent caries occurring in marginal defects wider than 50 microns. These defects occurred most often in developmental grooves and appeared related to a marginal excess of material. Horowitz et al[36] evaluated with a television microscope the smooth surface mesio-buccal proximal margins of amalgam restorations placed in maxillary second primary molars. The results indicated that at one year, the occlusal area of this margin could develop marginal defects as wide as 77.7 microns. The gingival area had defects as wide as 54.8 microns at one year. No caries were reported, and no correlation was made between the results and possible future findings.

At present it is apparent, that from a macroscopic point of view, it may be that recurrent caries is unrelated to the inherent marginal deterioration of amalgam.

Amalgam Adaptation

The adaptation of amalgam to the walls of the cavity preparation is another weakness of the material. Wing[37] has demonstrated that amalgam appears to con-

tact the walls and the floor of the preparation in a very limited number of places. This space along the tooth-material interface, as measured from longitudinal sections using a reflected light microscope and a filar eyepiece, ranged from 7 to 32 microns. The space at the cavo-surface margin area ranged from 16 to 45 microns.

In a recent study[38] using a ultrasonic probe, the interface space between tooth and amalgam was measured and found to vary from less than 1 micron up to 15 microns. Even this smaller range provides enough space to permit the passage of bacteria, carbohydrate solutions and organic acids.

Initially this space creates a severe micro-leakage. In vitro studies[39-42] show that, during the first few days, penetration can occur completely around the restoration. However, the leakage markedly diminishes with time. This improvement in seal is thought to be due to the formation of corrosion products and organic molecules which mechanically fill the interface space. In vivo studies[43] also show an improvement in seal. But long-term in vivo studies demonstrate that the leakage pattern can vary greatly. Going[44] showed leakage ranged from none to extreme, with the restorations well distributed throughout the range. Eighty percent of the five-year in vivo restorations evaluated by Baumgartner[22] gave evidence of leakage. The leakage and absence of leakage were noted in both groups of clinically acceptable and unacceptable restorations.

The initial seal of amalgam restorations can be improved by using a copal cavity varnish.[40-42] Gilmore,[42] though, has reported that after extended time intervals, copal varnish lined restorations were not superior to unlined restorations in terms of leakage.

It is apparent that amalgam restorations show leakage initially and can continue to leak. Also the interface space is wide enough to allow the passage of organisms, carbohydrate solutions and organic acids involved in the caries process. However, there is no clinical evidence that the inherent micro-leakage associated with amalgam restorations is related to recurrent caries.

Since Jorgensen found that a marginal defect had to be of 50 microns or more before there was microscopic evidence of recurrent caries, the main consideration with respect to the problem of recurrent caries may be the magnitude of the leakage, and not the mere fact of leakage itself.

In summary, concerning the inherent weaknesses of amalgam, clinical studies evaluating the performance of various amalgam alloys and manipulative procedures have reported no recurrence of caries. These studies have been well controlled in cavity design and in the manipulation of the materials. They demonstrated the potential performance of amalgam restorations, and well support the statement, "few inferior dental alloys are marketed;. . . observed failures may be attributed to factors other than the material itself."[45]

2. Enamel Cavo-surface Margin

Enamel is a brittle material and the enamel cavo-surface is friable. The possibility exists that the breaking away of enamel rods may be associated with recurrent caries. Clinicians place much emphasis on an adequate resistance form that protects the tooth and the restorative material against fracture. Undermined

enamel or weakened areas of the tooth lacking sufficient support by dentin must be removed as they are subject to fracture, which would leave large marginal discrepancies.

The cavo-surface margin should form a 90° angle with the enamel surface. This reduces the possibility of grossly undermining the enamel rods and gives maximum bulk to the margin of the amalgam restoration. Finishing the enamel margin should remove irregularities of the cut enamel surface which may consist of undermined or weakened enamel rods. Charbeneau[46] has demonstrated that the marginal irregularities produced by a 701 carbide bur can cause some 10 enamel rods in depth to lose their own support or the support of the underlying dentin.

No conclusions have been reached as to the instruments or procedures capable of producing the smoothest margins. Various studies have indicated that hand instruments and rotary instruments do result in differences in enamel surface irregularities.[46-50] But even so, as Fanibunda[51] implied in his photomicrographic evaluation of dental instruments on enamel, there are enough variables between operators and conditions so that the same instrument or procedure is capable of producing varying types of margins and surfaces. Scott and O'Neil[52] examined the microstructure of cut enamel and dentin and found no marked differences in the texture of the surface prepared with different instruments.

Clinically, fractured enamel margins are not common, except in large Class II restorations in primary molars[53] where, due to tooth morphology, the proximal

buccal or proximal lingual enamel margins often lack adequate dentin support. Broadhurst,[24] in examining 1,364 first permanent molar occlusal restorations, found only 18 enamel fractures, and in 471 second permanent molar occlusal restorations he found only 3. Ten of the enamel fractures showed caries, but it appeared that the fractures were due to the caries rather than the caries being due to the fracture. Jorgensen,[35] examining restorations at 72 times magnification, found enamel fractures to be common, but usually causing a defect less than 10 microns wide. Enamel fractures wider than 20 microns were very rare, less than one percent of the points evaluated along the cavity margin. Again Jorgensen reported no microscopic evidence of caries in marginal defects under 50 microns.

To recapitulate, minute enamel fractures do occur along with amalgam margin breakdown. However, no clinical relationship has been shown between this occurrence and recurrent caries. Enamel fractures large enough to be visible to the unaided eye appear to be due to inadequate support for the enamel, either because of recurrent caries or an inadequate resistance form that left undermined or weakened areas of enamel.

3. The Dental Operator

Research and clinical experience have developed dental amalgam alloys and procedures that make possible successful amalgam restorations. Success depends upon conscientious attention to detail in cavity design and manipulation of the materials.

The dental curriculum devotes much time to teaching the concepts, principles and psychomotor skills necessary to achieve success with amalgam. And yet, there must be a problem in the transfer of this learning from the dental school environment to the private practice. Numerous articles[7-9, 54-64] indicate that it is the dental operator failing to use amalgam to its full potential that causes recurrent caries and amalgam failures.

Healey and Phillips[7] reported that 53.5% of the amalgam restorations judged as failures gave evidence of recurrent caries. Improper cavity design was found to be the causative factor in 96% of these restorations, while use of amalgam where not indicated accounted for the other failures due to recurrent caries. Lack of extension for prevention was by far the most frequent violation in cavity design. Amalgam fractures, dimensional changes, and pulp or periodontal involvements comprised the remaining 46.5% failures. These failures were due primarily to faulty manipulation of the material and procedures. Healey and Phillips concluded that clinical success depends upon many factors, most of which the operator can control.

Easton[8] evaluated 415 amalgam restorations indicated for replacement because of recurrent caries. Lack of extension for prevention was evident in 81% of the restorations. Other causes for the recurrent caries were improper carving and lack of correct finish and polish. He felt that most amalgam failures are due to factors entirely under the control of the dentist.

One thousand amalgam failures were examined by Moss[9] for cause of failure. Recurrent caries caused 540 failures. Of these, 528 were due to faulty cavity design; twelve were due to material failure. Incorrect cavity design caused 838 of the 1,000 failures. Lack of adequate extension was the most common fault in cavity design. Amalgam failures, Moss states, are due to shortcomings of the operator, not the material.

In summary there appears to be a causal relationship between recurrent caries and inadequacies in preparation of the tooth, manipulation of the material, or misjudgment in its use. These are factors which the operator can control; and in seeking solutions to the problem of recurrent caries, it is important to begin with what is already known.

4. The Dental Patient

Markley[65] has stated that the patient shares in the responsibility for a successful restoration. If caries control measures are not practiced, even the well-placed restoration can fail. Supporting this opinion, Broadhurst[24] found in his study of recurrent caries that the rate of recurrence was directly related to the level of caries activity (as determined by DFS per child). Laswell[23] also concluded that the greater the probability of a primary lesion, the greater the probability of recurrent caries.

So the patient also has an important role in the control of recurrent caries. He must aid by practicing good oral hygiene and by controlling dietary factors which are predisposing to caries.

In summarizing the four areas that have been considered as possible causes of recurrent caries, it is evident that recurrent caries is not so much related to the inherent weaknesses of the amalgam restoration or to the friability of the enamel cavo-surface margin as it is to the quality of the operative procedures and the level of caries activity.

Prevention of Recurrent Caries

Preventive measures must begin with the operator designing a cavity preparation that eliminates the primary carious lesion and extends the preparation to areas where the enamel is less susceptible to the patterns of caries attack. Meticulous care is also required in manipulating the amalgam to achieve maximum performance of the material. This precludes material deterioration which can cause conditions predisposing to higher caries activity and susceptibility along the cavo-surface margin. The patient should also be shown how he can effectively alter recurrent caries susceptibility by careful diet and hygiene practices which reduce the level of caries activity.

Fluorides should be considered in the prevention of recurrent caries. The clinical effectiveness of fluorides, in community water supplies, in topical therapies, and in prophylactic pastes and dentifrices has been repeatedly established.

Fluoride appears to afford better protection for smooth surfaces than occlusal surfaces.[66-73] The incidence of pit and fissure caries is less influenced by fluorides. Defective amalgam margins and unextended grooves would closely simulate

natural pits and fissures. Therefore, conventional means of administering the fluorides may have little effect in preventing recurrent caries.

Clinical studies and observations have shown that silicate restorations are less susceptible to recurrent caries than other types of restorative materials.[1,4-6] This occurs despite the fact that silicate restorations have minimal extension into areas of tooth less susceptible to caries and the solubility of the material leaves poorly adapted and exposed margins.

Volker[1] was the first to suggest that silicate restorations contained one or more soluble factors that tend to inhibit the carious process. In his study those factors markedly reduced the enamel solubility. He felt that fluorine might be one of the responsible factors, since fluorides are present in silicate cement in concentrations of over 10%. Also Crowell[74] had shown that soluble fluorides could be removed from silicate powder immersed in distilled water for two months.

Phillips and Swartz,[2] in their early studies of enamel solubility before and after contact with silicate cement, concluded that silicate restorative materials did reduce enamel solubility, and that the reduction could be attributed to the fluoride in the silicate. A silicate cement free of fluoride actually increased enamel solubility. They felt that the mechanism was comparable to the topical action of a fluoride solution. The increased resistance of the enamel to acid attack was the probable reason for the lower incidence of recurrent caries about silicate restorations.

Norman et al[3] further substantiated the findings of Phillips and Swartz. He also quantitatively evaluated the release of fluoride from various materials and the subsequent fluoride enamel uptake. When the data on fluoride enamel uptake were compared with those on enamel solubility, there was a relationship between fluoride uptake and reduced enamel solubility. Also the materials releasing the most fluoride produced the highest fluoride enamel uptake. However, when large quantities of fluoride are released, only a small percentage of it is actually taken up. When a smaller amount is released, a greater percentage of the released fluoride is taken up by the enamel. There apparently is a point of diminishing returns, beyond which increasing the availability of fluoride produces little further reduction in enamel solubility.

The reduction of enamel solubility by fluoride may be only one mode of action accounting for the lower incidence of recurrent caries about silicate restorations. The anticariogenic action may be due to the ability of fluorides to increase the mineralization potential of calcifying solutions toward enamel, and thus aid in remineralization of initial decalcified lesions.[75-77] Another mode, as Volker[1] first indicated, is that the fluoride leached from silicate restorations interferes with the metabolism of oral microorganisms. Norman et al[78] have demonstrated that plaque grown on silicate cements differs from plaque grown on fluoride-free restorative materials. The carbohydrate-nitrogen ratio was higher, indicating that either carbohydrate is metabolized less efficiently or fewer bacteria are present in plaque associated with silicate restorations.

Stookey,[79] in reviewing the literature concerning the mechanisms of fluoride in oral flora metabolism, suggested that it is not so much a bacteriostatic influence as it is an inhibitory influence upon the rate of acid production by the oral flora. Concentrations of fluoride as low as 0.5ppm affect the acid production. Dental plaque can accumulate and concentrate fluoride from six to nearly 180ppm. To inhibit bacterial growth, 250ppm are required.

Though the exact mode of action of the fluoride ion released from silicate restorations is still debated, the ion is accepted as a factor responsible for reducing the susceptibility of these restorations to recurrent caries.

Using this concept as the rationale and based upon the previously mentioned laboratory studies of Phillips, Swartz and Norman,[26] fluoride compounds have been added to two commercially available resins,[a,b] so as to impart a potentially anticariogenic property to them. However, no clinical studies have evaluated the effectiveness of doing so.

As a possible aid in reducing recurrent caries about amalgam restorations, Soremark et al[80] investigated adding fluoride compounds to a zinc oxide, calcium hydroxide, polystyrene cavity liner. The liner reduced the acid solubility of the dentin test specimens. Fluoride release became insignificant after 21 days.

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[a]Bonfil - L.D. Caulk Co., Wilmington, Del.

[b]Sevriton Simplified - Amalgamated Dental Trade Distributors, Ltd., London, Eng.

A one-year clinical study by Alexander[81] indicated that applying a stable 30% stannous fluoride solution to the cavity preparation for 15 seconds could reduce the incidence of recurrent caries about amalgam restorations by 59%.

Adding fluoride compounds to the dental alloy itself is now receiving more consideration. Earlier studies of this type dealt primarily with the effect the compound might have on the physical and working properties of the alloy. Rowe and Kramer[12] indicated that stannous fluoride at a concentration of 300ppm did not appear detrimental to the amalgam. Innis and Youdelis[13] found that the mechanical properties of amalgam containing calcium fluoride in amounts less than 0.5% by weight differed little from those of the control amalgam. The amalgams containing 0.5% weight or less calcium fluoride had a fairly uniform distribution of the calcium fluoride. As the concentrations increased, the calcium fluoride tended to segregate and clump, reducing the compressive strength of the amalgam.

A more extensive laboratory and clinical study of an amalgam containing 0.5% by weight stannous fluoride was made by Minoguchi et al.[11] They found a slight decrease in compressive strength and hardness due to the 0.5% stannous fluoride. There was no difference in dimensional change and corrosion resistance. The release of the fluoride from the amalgam was rapid. One-third of the amount released occurred during the first ten days. Fluoride uptake was also demonstrated. The fluoride content of enamel was increased 152.7% after two days. It was increased 127.3% after six months. The results of the clinical study showed a

lower incidence of recurrent caries about the fluoride-containing restorations. At 1.5 years the fluoride-containing restorations had no recurrent caries, whereas the fluoride free restorations showed a 5% incidence. At three years, the incidence of recurrent caries was 5.3% with fluoride, and 18.3% without. Five years gave an incidence of 15.9% with fluoride; 40% without.

Buonocore and Tani[14] evaluated the effect that stannous fluoride at 0.5% by weight might have on marginal leakage. They concluded that it caused no change in the leakage patterns. Their tests of compressive strength also showed a slightly reduced strength for the fluoride-containing alloy.

Evaluating alloys containing 0.1% by weight stannous fluoride or sodium fluoride, Custer and Coyle[15] found that the compressive strengths for the alloys containing either fluoride salt were not significantly different from those for the non-fluoride alloy controls. At concentrations over 0.1% there was a reduced compressive strength.

Jerman[10] paired an amalgam containing 300ppm stannous fluoride with the same amalgam free of fluoride. The restorations were placed in the teeth of albino rats. The rats were fed a cariogenic diet for 60 days. Significantly fewer recurrent caries were observed at the margins of the fluoride-containing restorations.

Studies[10] at the U.S. Air Force School of Aerospace Medicine evaluated sodium fluoride, stannous fluoride, stannous chloride, zirconium tetrafluoride, and chromium trifluoride as possible additives to amalgam. Stannous fluoride gave the

greatest reduction in enamel solubility. Also, 1.5% by weight stannous fluoride was determined to be the optimum amount to add. Lower concentrations afforded little reduction in enamel solubility, while higher concentrations significantly altered the physical properties of the amalgam.

Jerman[10] further investigated amalgam containing 1.5% by weight stannous fluoride. In addition to enamel solubility, he evaluated the fluoride content of enamel adjacent to restorations containing or free of the stannous fluoride. The fluoride content of the enamel was increased 79% and the enamel solubility was reduced 68% by the fluoride-containing amalgam. The 1.5% by weight stannous fluoride slightly reduced the compressive and tensile strength of the amalgam, but had no effect on setting dimensional changes.

A clinical study[82] evaluating this fluoride-containing alloy, over a two-year period showed that the stannous fluoride additive did not affect the clinical behavior of the amalgam. Also no recurrent caries has been observed with either the test or control alloy.

Recently one point of concern has been raised on adding fluoride to amalgam. Stoner, Senti and Gileadi[83] have demonstrated in the laboratory with electrochemical measurements that 1.5% by weight stannous fluoride added to spherical amalgam caused a deterioration of the corrosion resistance of the amalgam. This was probably due to the dissolved stannous fluoride leaving a more porous amalgam surface. No clinical correlation has been made, but decreased corrosion resistance should be a property tested when evaluating fluoride-containing amalgams.

Though sufficient clinical evidence is lacking, fluoride additives to dental materials and topical fluoride liners are receiving attention as a means of reducing the incidence of recurrent caries about amalgam restorations. In addition to evaluating the anticariogenic property of the fluoride and the effect of the fluoride compound on physical properties, it is necessary to consider the effect the released fluoride may have on pulp response and tissue tolerance.

Early studies involving the effect of fluoride on the pulp were concerned with the use of fluoride as a desensitizing agent for hypersensitive dentin. Lefkowitz and Bodecker[84] placed dry sodium fluoride in teeth of dogs in amounts of 18, 36 and 72 mgs. At these amounts the pulps of all the experimental teeth showed evidence of pathology, the degree of reaction dependent on the size and duration of the dose. The larger doses resulted in complete pulp necrosis. When nine mgs. were placed in human teeth, at 24 hours there was localized abscess formation confined to the area of the pulp in contact with the tubules which were in contact with the sodium fluoride. The rest of the pulp was hyperemic.

Rovelstad and St. John[85] applied sodium fluoride to freshly cut human dentin in a 4% solution, as a paste, and as crystals moistened in distilled water. The sodium fluoride was applied for five minutes. Histologic examination showed that the inflammation after fluoride treatment was more severe in all instances than in the control teeth. The pulp gave evidence of vacuolization of the odontoblastic layer, round cell infiltration, hyperemia and hemorrhage.

From a study in which sodium fluoride was added to a zinc oxide, zinc sulfate, corn starch filling material in concentrations of 1 to 4% by weight, Maurice and Shour[86] concluded that the filling material produced no permanent untoward effects on the pulp, and that small amounts of sodium fluoride might be incorporated into filling materials without harming the pulp. A 4% sodium fluoride topical solution applied for five minutes to freshly cut dentin also would not be likely to injure the pulp.

A 10% stannous fluoride solution was applied to freshly cut dentin of rat molars for 30 seconds. Massler and Evans[87,88] reported no immediate or long-term injurious reaction to the odontoblasts or pulp. No significant effects were seen even when the stannous fluoride solution was applied directly to the pulp through small exposures.

Using dogs, Andres et al[89] applied a stable 30% stannous fluoride solution to freshly cut dentin for one minute. No adverse pulpal response was detectable upon histologic examination.

A fluoride containing calcium hydroxide, zinc oxide, and polystyrene cavity liner was evaluated by Brannstrom.[90] No significant difference was found in the reaction of the pulp to the control or the test liner.

Sperber[91] determined the biologic reactions of rat connective tissues to calcium fluoride containing amalgams. He indicated that the addition of 1% by weight to amalgam caused prolonged irritation to the tissues. Adding 0.5% by

weight or less of calcium fluoride caused no undue inflammation response and was considered safe for clinical use.

In conclusion, the reports suggest that adding fluoride to materials or using it as a topical liner causes no adverse tissue response and may be safely considered as a means of preventing recurrent caries.

METHODS AND MATERIALS

The dental alloy evaluated in this project was the L. D. Caulk Spherical Alloy, to which was added stannous hexafluorozirconate at 0.5% by weight[a]. The control dental alloy[b] was the same alloy, fluoride free. The alloys were manipulated according to the manufacturer's directions.

Laboratory tests provide data that can relate the physical properties of one material to another. They provide a method to screen or product test new materials. Laboratory test results, also, can indicate potential clinical performance of a material. But actual clinical performance can not be determined directly from laboratory testing alone. Controlled clinical studies are necessary to adequately evaluate material performance when subjected to the demanding environment of the oral cavity. Therefore, there were two phases to this study: a laboratory phase and a clinical phase.

The laboratory phase consisted of tests that evaluated the affect stannous hexafluorozirconate might have on the physical properties of the dental alloy, as well as the release and uptake of fluoride and its effect on enamel solubility. The clinical phase evaluated the affect the fluoride compound might have on the clinical performance of the alloy, and its ability to inhibit or reduce the prevalence of recurrent caries.

The clinical performance of the restorative materials was compared with the laboratory properties, with an attempt to establish whether there was any significant relation between them.

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[a]Batch #Y4-34-1
[b]Batch #1264-601010

Part I: Laboratory Phase

The amalgam specimens for the following tests were made from mixes using two 300 mg pellets and 510 mg of mercury. This gave a mercury content of 46%. Each mix was triturated 18 to 20 seconds in a high speed amalgamator.[a] The amalgam was not mulled, nor was any mercury expressed from the mix prior to condensation. All specimens were hand condensed.

Fluoride Release

Discs 15 mm in diameter and 2 mm thick were prepared from the control and test alloys. One hour after preparation, the discs were suspended by stainless steel wires in crucibles containing 20 ml of distilled water. The solutions were changed at 24-hour intervals over a period of five days. The solutions were quantitatively analyzed for fluoride using a fluoride ion electrode.[b] This method of evaluation gave data concerning both the rate of dissolution of the fluoride and the total amount released. Five specimens of each amalgam were evaluated for fluoride release.

Enamel Fluoride Uptake

The procedure used for determining enamel fluoride uptake was that which has been described by Norman et al[92] and Swartz et al.[93] Briefly, sound extracted cuspids were cleaned and buffed with levigated alumina. A 0.4 mm thickness of surface enamel was removed from one half of the labial and adjacent proximal surface by means of a diamond instrument in a hand piece fitted to a jig that controlled the

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[a] Wig-L-Bug, Cresent Dental Mfg. Co., Chicago, Ill.

[b] Orion Ionalyzer, Model 96-09, Orion Research Inc., Cambridge, Mass.

cut. The cut enamel was collected, dried, dissolved in hydrochloric acid buffered to a pH of 5, and then analyzed for fluoride with the fluoride ion selective electrode.

The amalgam was then placed and held against the other half of the labial surface and its proximal surface. The tooth and amalgam was next stored in distilled water for 24 hours and for one, two, and four weeks. The storage temperature was 37°C and the water was changed each day. At the end of each time interval, the amalgam was removed and the underlying 0.4 mm of enamel was removed and analyzed for fluoride.

By this method each tooth served as its own control. The fluoride content of the enamel before and after exposure to the amalgam could be compared. The results of the control amalgam compared with the results of the test amalgam would indicate the fluoride uptake produced by the stannous hexafluorozirconate. A minimum of 10 specimens of each amalgam for each time interval were evaluated.

Enamel Solubility

Enamel solubility was determined using procedures described by Phillips and Swartz[2] and Swartz et al.[93] Briefly, sound extracted central incisors were cleaned and buffed with levigated alumina. A selected tooth was then sealed with a combination of wax and electrical tape, except for a 5.5 mm circle of the labial surface. The initial solubility of the area of the exposed enamel was measured by determining the amount of calcium dissolved during a 30-minute immersion in 10 ml of pH4 acetic acid. Calcium was analyzed by the method of Solomon, Cabrio and Smith.[94]

After removal of the wax and tape, the labial surface was again buffed with levigated alumina until all traces of the acid etch were removed. The amalgam was then placed and held against the labial surface. After storage in a humidor for one hour, the tooth and amalgam were transferred to a test tube of distilled water and stored at 37°C for one, two, and four weeks. The water was changed daily. After each time interval, the amalgam was removed; the tooth resealed in wax and tape, exposing the same area of enamel as before; and the calcium solubility in acetic acid measured.

Each tooth served as its own control so that the solubility of the enamel before and after contact with the amalgam could be compared. The difference between the results for the control and test amalgam would indicate the effect the stannous hexafluorozirconate had on enamel solubility. A minimum of seven specimens of each material for each time interval were evaluated.

Compressive Strength

Compressive strengths of the control and test amalgams were measured at intervals of 15 minutes, one hour, 24 hours, and one week. The specimens were hand condensed into a mold space 8 mm in length and 4 mm in diameter. Five specimens of each alloy were evaluated at each time interval. The specimens were stored in air at room temperature for the designated period. The force required to break each specimen was recorded on a Riehle testing machine, using a head speed of 0.02 inches per minute.

Tensile Strength

The tensile strength of the control and test amalgams were evaluated using the diametral-compression test as indicated in the ADA specification #1 for alloy for dental amalgam, Section 4.3.5.[95] The test intervals and conditions were the same as those described for the compressive strength test.

Flow

The specimens were made by hand condensation of the amalgam into a mold space 8 mm long by 4 mm in diameter. The specimens were stored and tested at 37±1° C. Two hours and 45 minutes after start of trituration, the length of the specimens were measured. Three hours after the start of trituration, the specimens were subjected to a constant axial pressure of 1450 psi, the load being maintained for 21 hours, after which the speciment length was measured again. The shortening of the specimen was used to calculate the percentage of flow. The average flow value of four specimens, reported to the nearest 0.1%, represented the flow value for the amalgam.

Dimensional Change During Hardening

Specimens were made by hand condensation into a conical tipped mold space that gave a specimen 10 mm long by 5 mm in diameter. The specimens were evaluated for change in length with an interferometer 15 minutes and 24 hours after the start of trituration. During the test, the temperature was 37±1° C. The average change in

length of six specimens, reported to the nearest 0.01% represented the dimensional change during the hardening for the amalgam.

Hardness

Surface hardness of the control and test amalgams was evaluated with a Knoop diamond indenter in a Tukon testing machine. Flat disc specimens, one-eighth inch thick and one-fourth inch in diameter, were tested at intervals of 15 minutes, one hour, 24 hours, and 48 hours after start of mixing. Following the 48-hour test, the specimens were polished, using flour of pumice and tin oxide, and then retested. A 100 gm indenter load was used at the 15-minute interval, 200 gms at one-hour, and 300 gms at 24 and 48 hours. The polished specimens were also tested with the 300 gm load. Five specimens of each amalgam were evaluated. The specimens were stored in air at room temperature during the time intervals.

Marginal Leakage

The effect stannous hexafluorozirconate may have on the marginal leakage pattern of the amalgam was evaluated using the Ca^{45} radioisotope technique.[42] Class V cavity preparations were cut in sound, extracted human cuspids that had been stored in water. The preparations were not coated with a varnish since, clinically, a varnish would not be used with a fluoride-containing amalgam because the varnish would inhibit the fluoride uptake by the enamel. The placement and finish of the control and test amalgams simulated clinical methods.

Seven specimens were fabricated for each alloy and stored in water at 37°C for one week. At that time marginal leakage was evaluated. A second set of seven specimens were evaluated at seven days after placement of the restorations; however, during this time the specimens had been thermocycled from a hot (112°F) and a cold (60°F) water bath 2500 times, with alternate immersion occurring every 30 seconds.

The autoradiograph of the specimens were evaluated and compared for marginal leakage by two examiners.

Tarnish and Corrosion

A rotating disc was used to cycle polished specimens of the control and test amalgams through a 0.05% solution of sodium sulfide at a rate of one revolution per minute. The specimens were polished on a felt wheel using flour of pumice and tin oxide. Nine pairs of specimens were tested. Evaluations for tarnish and corrosion were made over a two-week period. Evaluations consisted of a visual and a microscopic 25X comparison between paired specimens as to which showed the least signs of tarnish and corrosion. The evaluations were made by two examiners.

Evaluation of Exfoliated Primary Teeth

Study restorations placed in primary teeth will be examined upon exfoliation at 70X for marginal adaptation and recurrent caries. The primary teeth will also be sectioned at areas of marginal defects and examined for signs of recurrent caries.

Since it is anticipated that no restored primary teeth will be lost until about three years from now, this information will not be a part of this thesis.

Part II: Clinical Phase

The clinical phase of this study was based upon methodology and criteria developed by the former Materials and Technology Branch, Division of Dental Health, National Institutes of Health, Department of Health, Education, and Welfare.[31,32, 96-101] Briefly, the project was designed as a comparative study with the fluoride-free alloy serving as a baseline control for the evaluation and comparison of the fluoride-containing test alloy. Though the materials were used in a manner representative of a private practice, a procedure guide was formulated for each material so as to standardize methods, and eliminate as nearly as possible human variables in the manipulation of materials and procedures.

The test and control alloys were placed in pairs, by the same dentist, in the same patient, at the same appointment. A randomization scheme was used to determine which member of the pair received which material. By these methods each patient served as his own environment and habit control, eliminating the need to determine inter-patient variables.

Upon completion of 98 pairs of restorations, a baseline examination of the restorations was made by two examiners who had been trained in the use of specific evaluation criteria that defined and measured the clinical characteristics of marginal adaptation, surface tarnish and corrosion, and recurrent caries. A one-year recall

examination of the restorations was also made, and subsequent annual recall examinations will be made to evaluate and compare the performance characteristics of the test and control restorations.

The evaluation results obtained for each clinical characteristic at the baseline and at the annual recall examination constituted the data upon which clinical performance or changes in the clinical conditions of the test and control restorations were determined as a function of time.

The conduct of the clinical phase of the study and the procedure guides developed for using the materials are presented in more detail in the following section.

Population Studied

Children residing at the Soldiers' and Sailors' Childrens' Home, Knightstown, Indiana, comprised the patient population for the study. Selection of patients from this group was based on the need for adjacent, contralateral, or opposing pairs of Class I, II or V restorations in primary or permanent teeth. Each patient served as his own control, with one restoration of the pair being the fluoride-containing amalgam; the other, the amalgam without fluoride. This allowed a comparison to be made of the two materials while eliminating the need to determine inter-patient variables.

Ninety-eight pairs of restorations were included in the study. Paired restorations were placed during the same appointment. Only after both preparations were completed was the decision made as to which material was used to fill a particular preparation. This choice was determined by random selection.

Clinical Procedures

A local anesthetic was administered and a rubber dam applied for each patient. Cavity preparations followed the concept of conservative design. All non-coalesced pits and fissures contiguous to the carious lesion were eliminated. Whenever possible, the bucco-lingual width of the occlusal outline was formed within one-fourth to one-third of the intercuspal distance, and extended pulpally to a minimum of 1/2 mm into sound dentin. All margins were placed in sound tooth structure, in areas that were more easily cleansed and less susceptible to caries. When proximal caries were present, minimal extension was made bucally, lingually and gingivally. However, the contact area was removed sufficiently so that approximating tooth surfaces no longer contacted.

Outline form was established using a 330L high speed bur. Refining the preparation was done with a 330L slow speed bur. Therefore, internal line angles were rounded. When necessary, extensive caries was removed with either a four or eight round bur. In Class II preparations, the axial-pulpal line angle was rounded; proximal retentive grooves were not used.

The cavity preparations were cleansed using cotton pellets and water.

Where penetration into the dentin was greater than 1/2 mm, these areas were lined with a radiopaque calcium hydroxide preparation.[a] Two or three thin applications of a copal varnish[b] were made to the cavity preparation that received the fluoride-free dental amalgam, covering the dentin, enamel and cavo-surface margins. The

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[a]Dycal - L.D. Caulk Co., Milford, Delaware
[b]Copalite - Cooley and Cooley, Ltd., Houston, Texas

preparation receiving the dental amalgam containing the fluoride additive was not lined with the varnish since it inhibits the enamel fluoride uptake.

For Class II restorations, a T-band matrix was used. The band was contoured and then wedged at the gingival margin.

L.D. Caulk's spherical alloy was the control material. The same alloy containing stannous hexafluorozirconate at a concentration of 0.5% by weight was the test material. Both alloys were dispensed in pellet form. All mixes were made using two 300 mg pellets and 510 mg of mercury. This gave a mercury content of 46%.

Each mix was triturated 18 to 20 seconds in a high speed amalgamator.[c] The amalgam was not mulled, nor was any mercury expressed prior to condensation. One increment from an amalgam carrier was placed at a time and well condensed by hand.

Insertion was completed within three minutes. The amalgam was over-packed and carving began immediately upon completion of condensation.

Polishing of the restorations was done a minimum of 48 hours after insertion, using round burs to remove amalgam flash and wet flour of pumice and tin oxide for the final polish.

Clinical Data and Information Required

Using a Patient and Procedure Form, the following information was obtained at the time the pair of restorations was placed:

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[c]Wig-L-Bug, Cresent Dental Mfg. Co., Chicago, Ill.

a. Patient's name and age
b. Date of placement of restorations
c. Tooth number and surfaces restored
d. Restorative material used
e. Bases and liners used

Clinical Evaluation

The clinical characteristics of marginal adaptation, surface tarnish and corrosion, and recurrent caries were selected to evaluate the amalgam restorations included in this study. These characteristics reflect the functional performance of the restorations or specific areas of concern. The measuring of each of these characteristics was done through the use of rating scales. The rating scales consisted of judgment categories which were designed to detect changes in the clinical condition of restorations for each characteristic being assessed. The categories were arranged so that examiners arrived at a rating for each characteristic by making a series of bi-polar decisions which were operationally defined. Therefore, evaluation findings were based on specific and consistent judgments and not on individual personal impressions.

The selected clinical characteristics and their respective rating scale make up the criteria by which the restorations in this study were evaluated and compared. These criteria are presented in Figures 1, 2, and 3.

Since it was realized that some of the judgment categories within the clinical characteristics evaluated were fairly wide, a direct comparison was made whenever

two paired restorations were given the same rating, in order to determine which one was better in regard to that specific characteristic. The better restoration was appropriately recorded. This ranking allowed for a finer discrimination to be made between equally rated paired restorations, and enabled the detection of small but persistent differences.

On completion of 98 pairs of restorations, a baseline examination of the restorations was made by two examiners trained in the use of the evaluation criteria. This baseline evaluation was made within two months after the restorations had been placed. Though the examiners were aware of what amalgam alloys had been placed for evaluation, they were not informed during their examinations as to whether they were evaluating a test or a control restoration. Therefore the restorations were evaluated in a blind manner. Bitewing radiographs were taken at this time to establish a baseline for the presence of proximal caries.

A one-year evaluation was made after the restorations had been in service 12 to 14 months. Subsequent annual recall evaluations and bitewing radiographs will be made for a minimum of five years or until the primary teeth containing restorations are exfoliated.

Arrangements were made to have the exfoliated primary teeth sent to the Department of Dental Materials, I.U.P.U.I. School of Dentistry, where the restorations will be examined at 70X for marginal adaptation and recurrent caries. Areas of marginal defect will be sectioned and examined for signs of recurrent carries.

Data Collection and Analysis

The clinical examination results were recorded on a patient evaluation form. The rating at the baseline examination and at the annual recall examinations constituted the data for statistical analysis of changes and significance of changes in the clinical condition of the test and control restorations. A frequency distribution was prepared for the evaluation ratings and rankings for each material and characteristic evaluated. The results were analyzed using a binomial distribution for related scores, at a 95% level of confidence.[102,103]

RESULTS

Part I: Laboratory Phase

Fluoride Release

The amount and rate of fluoride released from the amalgam specimens are shown in Table IV, and summarized in Figure 4. The values recorded for the fluoride free control specimens were beyond the accuracy of the fluoride ion electrode and should be considered essentially as no fluoride released. The greatest dissolution of fluoride from the fluoride-containing test specimens occurred during the first 24 hours. The release diminished rapidly, such that by the fourth day the values recorded were beyond the accuracy of the fluoride ion electrode.

The total fluoride content of a test specimen was 1,742ppm, as determined from the percent fluoride present in the material and the specimen weight. Surface area of the specimen was 447.4 mm^2. Only about 0.44 percent of the total fluoride content of the specimen was released. It is evident that a very small quantity of fluoride becomes available for enamel uptake.

Fluoride Uptake

The fluoride content of the intact enamel surface specimens before and after treatment with the control and test amalgams are listed in Tables V and VI, and illustrated in Figure 5. Though the magnitude of change for individual teeth varied, there was a definite indication that the fluoride-containing amalgam increased the enamel fluoride content, whereas the fluoride-free amalgam reduced the enamel fluoride content.

The fluoride-free control amalgam caused about a one-third reduction in the enamel fluoride content over a one-month period of time. The fluoride containing amalgam produced a fluoride increase of about 25-30 percent during the first 24 hours to one week. After two weeks and one month, the fluoride content increased 107 percent and 161 percent respectively.

Enamel Solubility

The change in solubility of intact enamel surface specimens before and after treatment with the control and test amalgams are presented in Tables VII and VIII, and graphed in Figure 6. Again the magnitude of change for individual teeth varied, but definite tendencies were indicated. At the one- and two-week time intervals, the fluoride-containing amalgam reduced the enamel solubility of the specimens approximately 50 percent. At one month, it was reduced 61 percent. The fluoride-free amalgam appeared to have had little effect on altering the enamel solubility of the specimens.

Compressive Strength

The data for compressive strength are listed in Table IX and summarized in Figure 7. The data were analyzed using the t-test at the 0.99 level of confidence. At 15 minutes and one hour there was no significant difference between the compressive strengths of the two amalgams. The 24-hour and one-week results did show a statistically significant difference favoring the fluoride-free control amalgam. The

compressive strength of both amalgams was well above the minimal compressive strength of 45,000 psi considered necessary for a satisfactory amalgam.

Tensile Strength

Tensile strength data are shown in Table X and illustrated in Figure 8. The data were analyzed using the t-test at the 0.99 level of confidence. The results showed no statistically significant difference between the two amalgams for tensile strength at the time intervals of 15 minutes, one hour and 24 hours. However, at the one-week interval, there was a difference favoring the fluoride-free amalgam. Still the tensile strength of the fluoride-containing amalgam was in the area considered necessary for dental amalgam.

Flow

The results of the flow test are shown in Table XI. The addition of stannous hexafluorozirconate at 0.5% by weight did not appear to effect the 21-hour static flow properties of the amalgam.

Dimensional Change During Hardening

The dimensional change results are presented in Table XII. The contraction of the specimen was expected since this is a characteristic of spherical alloy. It is apparent from the data that the addition of the fluoride compound did not effect the dimensional change properties of the amalgam.

Hardness

The results of the hardness tests are listed in Table XIII, and illustrated in Figure 9. The data were analyzed using the t-test at the 0.99 level of confidence. At each time interval there was no significant difference between the surface hardness of either amalgam. The hardness of both amalgams at 48 hours and after polishing was in the accepted area of hardness of dental amalgam, 90KHN.

Marginal Leakage

The fluoride-free control specimens stored in water for seven days exhibited a leakage pattern typical of an unvarnished cavity preparation as represented by the autoradiographs shown in Figure 10. Leakage penetrated to the floor of the preparation. In the comparative autoradiographs, the fluoride-containing test specimens gave a less severe leakage pattern, even though the depth of leakage penetration was the same.

As illustrated in Figure 11, these respective leakage patterns were also evident after control and test specimens were thermocycled 2,500 times, with the thermocycling causing no increase in the severity of the leakage.

Tarnish and Corrosion

Figures 12 and 13 illustrate control and test amalgam specimens which had been cycled for two weeks through a 0.05% solution of sodium sulfide. The fluoride-containing specimens showed extensive brown-black discoloration and corrosion

associated with the entire margins of the specimens. The fluoride-free amalgam specimens had isolated areas of marginal discoloration and corrosion, these areas being of a much less severity than the fluoride-containing specimens. Though not well depicted on the photographs, the overall surface of the fluoride-containing specimens was more dull than the control specimens.

Evidence of the brown-black marginal discoloration was apparent at 24 hours with the fluoride-containing amalgam, increasing in severity throughout the 14 days. Signs of corrosion at the margins were present at 72 hours, again increasing in severity throughout the test period. By ten days, there were a few isolated areas of corrosion about the surface of the fluoride-containing specimens.

It wasn't until the tenth day of exposure to the sodium sulfide solution that the fluoride-free amalgam specimens gave evidence of discoloration and corrosion in a few areas about the margins of the specimens. It is apparent from these results that the addition of stannous hexafluorozirconate at 0.5% by weight did alter the corrosion properties of the spherical amalgam, with the marginal areas of the specimens showing a marked susceptibility to tarnish and corrosion.

Part II: Clinical Phase

Ninety-eight pairs of restorations were included in the study as follows: 43 pairs in permanent teeth - 20 Class I, 23 Class II; 55 pairs in primary teeth - 6 Class I, 49 Class II. The restorations were placed over a two-month period with the baseline evaluation made at the end of that two-month period. The one-year evaluation was made 12 months after the baseline.

One of the problems with clinical evaluation studies is that of patient recall. The childrens' home at Knightstown was selected as a study site because of its stable population. However, last year there was a large turnover of children resulting in a 45 percent loss in the study restorations. This is reflected in the data tables by the large number in the "Not Evaluated" column.

Marginal Adaptation

Table 1a presents the distribution of ratings for marginal adaptation. Inspection of the table reveals that there may be a more favorable performance by the fluoride-containing amalgam. However, the data must be arranged differently in order to conduct a test of significance. According to Cvar:[102]

> The first consideration is that test and control restorations occur in pairs which are not independent of each other, since both members of the pair occur in the same patient's mouth. Analysis must therefore be based on a test for related rather than independent events. The binomial test was selected as there were numerous "zero" differences which might place normal distribution of difference scores in doubt and thus violate the assumption for the t-test.
>
> The second consideration is that when more than one pair of restorations occur in a single patient, the pairs themselves are also related rather than independent events. Therefore it is necessary to arrive at a single overall score for each patient before the binomial test may be applied.

The arrangement and comparison of the marginal adaptation ratings as suggested by Cvar is shown in Table 1b. Applying the binomial distribution for related items indicate that, at the 0.05 level, there is no significant difference between the marginal

adaptation ratings for the test and control alloys.

The ranking data used to detect small differences between paired test and control restorations are presented in Table 1c, in the manner suggested by Cvar. Binomial distribution analysis for related items, at the 0.05 level, offers little evidence of differences in marginal adaptation.

In addition to rating and ranking marginal adaptation, the location of the breakdown in marginal adaptation was also recorded and is presented in Table II. Twenty-four percent of the restorations in primary teeth and 21 percent in permanent teeth gave evidence of marginal breakdown at one year. The breakdown tended to occur in specific areas of the restorations. In primary teeth, 67 percent of the marginal defects occurred in the occluso-proximal marginal ridge area. These defects occurred twice as often on the buccal margin as on the lingual margin. The findings are similar to those which have been reported by MacRae et al.[53] Marginal breakdown in the buccal and lingual grooves and in the mesial and distal fossae accounted for 27 percent of the marginal defects.

In the permanent teeth marginal adaptation defects in grooves and fossae made up 87 percent of the defects. Only 9 percent occurred in the occluso-proximal marginal ridge area. The high prevalence of marginal defects in the grooves and fossae can best be explained by these areas being more difficult to condense and finish, and, therefore, areas of higher mercury content, porosity, and marginal flash.

Surface Characteristics

The objective of evaluating surface characteristics was to assess the restoration for signs of tarnish and corrosion. The distribution of surface ratings are shown in Table IIIa. The arrangement of the ratings for statistical analysis is illustrated in Table IIIb. The results indicate no difference between the test and control amalgam in their resistance to tarnish and corrosion. The ranking data is shown in Table IIIc. Again, no difference between the amalgams is evident.

Referring to the distribution ratings in Table IIIa, it is apparent that about 50 percent of the restorations lost their high polish and luster, becoming dull within the two-month period between polish and baseline evaluation. At one year 97 percent of the evaluated restorations had a dull, smooth finish, which is characteristic of a year-old polished amalgam.

When there were signs of a brownish-black tarnish at one year, they occurred within the gingival third of the proximal surface, and were usually present on both the test and control restorations. The tarnish appeared to be related to local oral environmental factors, as an accumulation of materia alba. Evidence of pitting was present on one restoration, and that occurred in an area where a thin cusp of enamel fractured, exposing the underlying amalgam which had not been carved and polished.

Caries

Recurrent caries is defined by the Federation Dentaire Internationale[104] as a positively diagnosed carious lesion occurring at the margins of an existing restoration.

The criteria used in this study to determine a positive recurrent carious lesion are described in Figure 3. Using these criteria, at one year, none of the evaluated restorations had caries associated with the margins. Also, none of the recorded areas of breakdown in marginal adaptation were of a nature to cause an explorer to "catch" and resist removal or showed signs of decalcification or undermining.

TABLES AND FIGURES

TABLE Ia.

Distribution of Ratings for Marginal Adaptation,
Spherical Alloy (S) Versus Spherical Alloy with Fluoride (SF)

Examination	Alloy	Total	Ratings A	B	C	D	Not Evaluated
Baseline	S	98	78	6			14
	SF	98	79	5			14
One Year	S	98	29	25			44
	SF	98	35	19			44

TABLE Ib.

Comparison of Ratings for Marginal Adaptation by Patient,
Spherical Alloy (S) Versus Spherical Alloy with Fluoride (SF)

Examination	Total	Same Rating	S-Rated Better	SF-Rated Better	Not Rated
Baseline	43	29	4	4	6
One Year	43	12	4	10	17

TABLE Ic.

Comparison of Rankings for Marginal Adaptation by Patient,
Spherical Alloy (S) Versus Spherical Alloy with Fluoride (SF)

Examination	Total	Same Ranking	S-Ranked Better	SF-Ranked Better	Not Ranked
Baseline	43	25	6	6	6
One Year	43	8	5	13	17

TABLE II

Location of Breakdown in Marginal Adaptation at One Year

	Primary Teeth	Permanent Teeth
Number of Teeth	110	86
Number with Defects	26	18
Location of Defects		
occluso-proximal marginal ridge area		
Buccal	16	1
Lingual	9	1
	25	2
grooves and fossae	10	19
Other	2	1
Total Defects	37	22

TABLE IIIa.

Distribution of Ratings for Surface Characteristics,
Spherical Alloy (S) Versus Spherical Alloy with Fluoride (SF)

Examination	Alloy	Total	Ratings A	B	C	D	Not Evaluated
Baseline	S	98	41	43			14
	SF	98	41	43			14
One Year	S	98	1	47	5	1	44
	SF	98	2	45	7		44

TABLE IIIb.

Comparison of Ratings for Surface Characteristics by Patient,
Spherical Alloy (S) Versus Spherical Alloy with Fluoride (SF)

Examination	Total	Same Rating	S-Rated Better	SF-Rated Better	Not Rated
Baseline	43	32	3	2	6
One Year	43	20	3	3	17

TABLE IIIc.

Comparison of Rankings for Surface Characteristics
by Patient, Spherical Alloy (S) Versus Spherical Alloy with Fluoride (SF)

Examination	Total	Same Ranking	S-Ranked Better	S F-Ranked Better	Not Ranked
Baseline	43	29	5	3	6
One Year	43	19	3	4	17

TABLE IV

Fluoride Release
(parts/million)

	With Fluoride					Without Fluoride				
Specimen	1 Day	2 Days	3 Days	4 Days	5 Days	1 Day	2 Days	3 Days	4 Days	5 Days
1	5.70	0.70	0.32	0.14	0.17	0.25	0.19	0.15		
2	6.90	0.55	0.26	0.14	0.14	0.21	0.20	0.17		
3	6.80	0.51	0.20	0.13	0.13	0.20	0.19	0.18		
4	7.70	0.81	0.32	0.20	0.15	0.19	0.19	0.17		
5	5.90	0.60	0.24	0.14	0.14	0.20	0.18	0.17		
Mean	6.60	0.63	0.26	0.15	0.15	0.21	0.19	0.17		
S.D.	0.73	0.11	0.05	0.02	0.01	0.02	0.01	0.01		

TABLE V

Fluoride Uptake By Enamel
From
Fluoride Containing Amalgam

	24 Hours			One Week		
Specimen	Control Side (p.p.m.)	Experimental Side (p.p.m.)	Per Cent Change	Control Side (p.p.m.)	Experimental Side (p.p.m.)	Per Cent Change
1	170	276	62	139	82	-41
2	204	184	-10	184	183	-01
3	143	221	55	147	168	14
4	197	256	30	158	136	-14
5	173	163	06	187	209	32
6	159	264	66	181	154	-15
7	225	301	34	168	230	37
8	191	208	09	124	171	38
9	203	202	00	149	171	15
10	268	472	76	189	201	06
11	47	115	145	127	315	148
12	151	152	00	158	83	-48
13	57	108	89	75	101	115
14	99	146	47	118	174	47
15	110	95	-14	95	145	53
16	114	102	-12	96	163	70
17	135	116	19	160	187	17
18	196	154	-21	93	131	41
19	183	218	19	95	148	56
20	154	113	-27	159	200	26
Mean	159	196	28	141	171	30
S.D.	40	60	40	26	48	38

TABLE V

(Continued)

Specimen	Two Weeks			One Month		
	Control Side (p.p.m.)	Experimental Side (p.p.m.)	Per Cent Change	Control Side (p.p.m.)	Experimental Side (p.p.m.)	Per Cent Change
1	138	334	142	182	364	100
2	100	377	276	203	447	120
3	178	297	57	142	493	247
4	139	240	73	124	669	440
5	115	279	143	112	360	221
6	154	322	109	252	451	79
7	176	263	49	180	557	209
8	248	371	50	132	458	247
9	166	305	84	187	472	152
10	122	268	120	161	506	214
11	78	164	110	129	265	105
12	42	157	274	99	273	176
13	107	209	95	140	264	89
14	135	293	117	117	161	38
15	113	224	98	102	372	265
16	104	137	32	192	657	242
17	128	274	114	120	252	110
18	114	142	24	136	185	52
19	104	164	58	147	272	85
20	76	157	107	143	181	26
Mean	127	248	107	150	383	161
S.D.	33	49	66	36	110	88

TABLE VI

Fluoride Uptake by Enamel

From

Fluoride Free Amalgam

Specimen	Two Weeks			One Month		
	Control Side (p.p.m.)	Experimental Side (p.p.m.)	Per Cent Change	Control Side (p.p.m.)	Experimental Side (p.p.m.)	Per Cent Change
1	134	102	-24	140	78	-44
2	132	104	-21	231	153	-34
3	149	93	-38	118	68	-42
4	280	220	-21	66	45	-32
5	262	186	-29	132	81	-39
6	241	154	-36	109	70	-36
7	203	167	-18	74	81	09
8	169	142	-16	179	100	-44
9	157	180	15	168	96	-43
10	92	85	-08	165	102	-38
11	188	129	-31			
12	103	64	-38			
13	151	119	-21			
14	235	136	-42			
15	81	71	-12			
16	58	64	10			
17	79	68	-14			
18	201	120	-40			
19	63	41	-35			
20	203	186	-08			
Mean	159	122	-21	138	87	-34
S.D.	61	43	15	47	27	15

TABLE VII

Solubility of Enamel
With
Fluoride Containing Amalgam

	One Week			Two Weeks		
Specimen	Control Ca-mg.%	Experimental Ca-mg.%	Per Cent Change	Control Ca-mg.%	Experimental Ca-mg.%	Per Cent Change
1	0.475	0.210	-55.6	0.526	0.262	-50.0
2	0.413	0.179	-56.6	0.460	0.258	-43.9
3	0.625	0.254	-59.5	0.488	0.200	-59.0
4	0.420	0.205	-51.3	0.446	0.228	-48.8
5	0.572	0.290	-49.3	0.388	0.200	-48.4
6	0.538	0.264	-50.9	0.520	0.276	-47.3
7	0.620	0.282	-54.5	0.542	0.254	-53.1
8	0.456	0.260	-43.0	0.412	0.198	-51.9
9				0.435	0.199	-54.2
10				0.461	0.242	-47.5
11				0.358	0.216	-39.8
12				0.373	0.179	-52.0
13				0.399	0.299	-25.2
14				0.375	0.202	-46.2
15				0.504	0.247	-51.0
16				0.491	0.251	-48.9
Mean	0.515	0.243	-52.6	0.448	0.232	-48.0
S.D.	0.080	0.038	4.8	0.058	0.032	7.2

TABLE VII (Continued)

Specimen	Control Ca-mg.%	One Month Experimental Ca-mg.%	Per Cent Change
1	0.430	0.134	-69.0
2	0.504	0.164	-67.0
3	0.454	0.134	-70.4
4	0.548	0.148	-72.9
5	0.442	0.150	-66.0
6	0.538	0.146	-72.8
7	0.398	0.154	-61.3
8	0.438	0.138	-68.4
9	0.470	0.238	-49.0
10	0.556	0.234	-58.0
11	0.412	0.208	-50.0
12	0.534	0.262	-50.0
13	0.482	0.162	-66.4
14	0.428	0.236	-45.0
15	0.622	0.262	-58.0
16	0.420	0.212	-49.5
Mean	0.480	0.186	-60.9
S.D.	0.062	0.046	9.3

TABLE VIII

Solubility of Enamel with Fluoride Free Amalgam

	Two Weeks		
Specimen	Control Ca-mg.%	Experimental Ca-mg.%	Per Cent Change
1	0.318	0.352	10.7
2	0.404	0.356	-11.9
3	0.568	0.510	-10.2
4	0.370	0.356	-03.8
5	0.448	0.410	-08.5
6	0.414	0.436	05.3
7	0.430	0.472	09.8
Mean	0.422	0.414	-01.2
S.D.	0.072	0.058	08.9

TABLE IX

Compressive Strength
(pounds/sq.in.)

Specimen	15 Minutes		One Hour	
	With Fluoride	Without Fluoride	With Fluoride	Without Fluoride
1	11,500	11,650	26,400	30,300
2	11,900	11,700	28,050	28,900
3	12,400	11,650	27,300	28,800
4	12,250	12,150	28,450	27,850
5	13,600	12,050	26,900	29,150
Mean	12,300	11,840	27,420	29,000
S.D.	791	241	834	878
"t" Value	1.32		2.92	
Confidence Level	0.78		0.98	

Specimen	24 Hours		One Week	
	With Fluoride	Without Fluoride	With Fluoride	Without Fluoride
1	50,500	56,750	52,250	59,750
2	50,750	57,500	53,000	57,750
3	50,000	57,750	52,750	59,750
4	51,000	58,000	52,750	59,250
5	50,250	57,250	52,500	59,500
Mean	50,500	57,450	52,650	59,200
S.D.	395	481	285	837
"t" Value	24.97		16.57	
Confidence Level	0.99		0.99	

TABLE X

Tensile Strength
(pounds/sq. in.)

	15 Minutes		One Hour	
Specimen	With Fluoride	Without Fluoride	With Fluoride	Without Fluoride
1	1200	1056	2925	2688
2	1119	1163	2900	3075
3	1238	994	3050	2625
4	975	1106	3000	3100
5	1238	1169	3150	2838
Mean	1154	1098	3005	2865
S.D.	111	74	101	217
"t" Value	0.94		1.30	
Confidence Level	0.63		0.77	

	24 Hours		One Week	
Specimen	With Fluoride	Without Fluoride	With Fluoride	Without Fluoride
1	8175	8275	8275	9425
2	8300	7950	8900	9750
3	7575	9250	7500	8675
4	7650	8575	7250	9325
5	7175	9425	7675	8650
Mean	7775	8695	7920	9165
S.D.	461	630	666	485
"t" Value	2.64		3.38	
Confidence Level	0.97		0.99	

TABLE XI

Flow
(3-24 Hours)

Specimen	Percentage of Flow	
	Fluoride Free Amalgam	Fluoride Containing Amalgam
1	0.8	1.0
2	0.8	1.0
3	0.9	0.9
4	0.9	0.9
Mean	0.85	0.95
S.D.	0.06	0.06

TABLE XII

Dimensional Change During Hardening

(15 min.-24 hrs.)

Specimen	Change in Microns/Cm	
	Fluoride Free Amalgam	Fluoride Containing Amalgam
1	-20.97	-16.66
2	-15.84	-23.45
3	-18.51	-16.38
4	-14.74	-19.13
5	-14.19	-12.56
6	-13.12	-15.42
Mean	-16.23	-17.27
S.D.	2.96	3.70

TABLE XIII

Surface Hardness (Knoop Hardness)

Specimen	15 Minutes		One Hour		24 Hours	
	With Fluoride	Without Fluoride	With Fluoride	Without Fluoride	With Fluoride	Without Fluoride
1	15.6	15.2	44.8	38.2	65.1	81.4
2	20.9	14.3	38.7	39.3	54.5	66.2
3	13.0	21.4	33.1	47.4	64.6	75.4
4	22.4	19.5	31.8	40.8	60.3	60.0
5	21.2	17.0	38.5	41.5	61.7	62.2
Mean	18.6	17.5	37.4	41.4	61.2	69.0
S.D.	4.1	3.0	5.2	3.6	4.3	9.1
"t" Value	0.49		1.42		1.74	
Confidence Level	0.36		0.81		0.88	

Specimen	48 Hours		48 Hours - Polished	
	With Fluoride	Without Fluoride	With Fluoride	Without Fluoride
1	70.0	81.4	94.1	94.1
2	66.7	67.8	81.4	98.7
3	67.8	85.8	98.7	91.5
4	65.1	65.1	83.6	86.6
5	62.2	66.2	87.4	90.7
Mean	66.4	73.3	89.0	92.3
S.D.	2.9	9.6	7.2	4.5
"t" Value	1.53		0.88	
Confidence Level	0.84		0.59	

FIGURE 1. Clinical evaluation criteria for marginal adaptation.

Rating	Characteristics
Alpha A	The explorer does not catch when drawn across the margin, from tooth to restoration and from restoration to tooth, or, if the explorer does catch, there is no visible crevice along the periphery of the restoration. The edge of the restoration appears to adapt closely to the tooth structure along the total periphery of the restoration.
Bravo B	The explorer catches and there is visible evidence of a crevice into which the explorer will penetrate, indicating that the edge of the restoration does not closely adapt to the tooth structure. The dentin or the base is not exposed, and the restoration is not mobile, fractured, or missing in part or in toto.
Charlie C	The explorer penetrates into a crevice indicating that a space exists between the restoration and the tooth structure. The dentin or the base is exposed at the periphery, but the restoration is not mobile, fractured, or missing in part or in toto.
Delta D	The restoration is mobile, fractured, or missing in part or in toto.

FIGURE 2. Clinical evaluation criteria for surface character.

Rating	Characteristics
A	The surface of the restoration has a smooth, shiny appearance.
B	The surface of the restoration has a smooth, dull appearance.
C	The surface of the restoration has a smooth appearance with signs of dark discoloration.
D	The surface of the restoration shows signs of dark discoloration which appear pitted.

FIGURE 3. Clinical evaluation criteria for recurrent caries.

Rating	Characteristics
A	There is no evidence of caries* contiguous with the margin of the restoration.
B	There is evidence of caries* contiguous with the margin of the restoration.

* An area at the restoration margin is carious if an explorer "catches" or resists removal after insertion with moderate to firm pressure, and is accompanied by one or more of the following:

a. Softness

b. Opacity at the margin, as evidence of undermining or demineralization

c. Etching or a white spot as evidence of demineralization

An area at the margin is also considered carious if the explorer does not "catch," but conditions b or c are present.

Figure 4. Fluoride release from the test and control amalgams at the time intervals evaluated.

AVERAGE FLUORIDE RELEASE

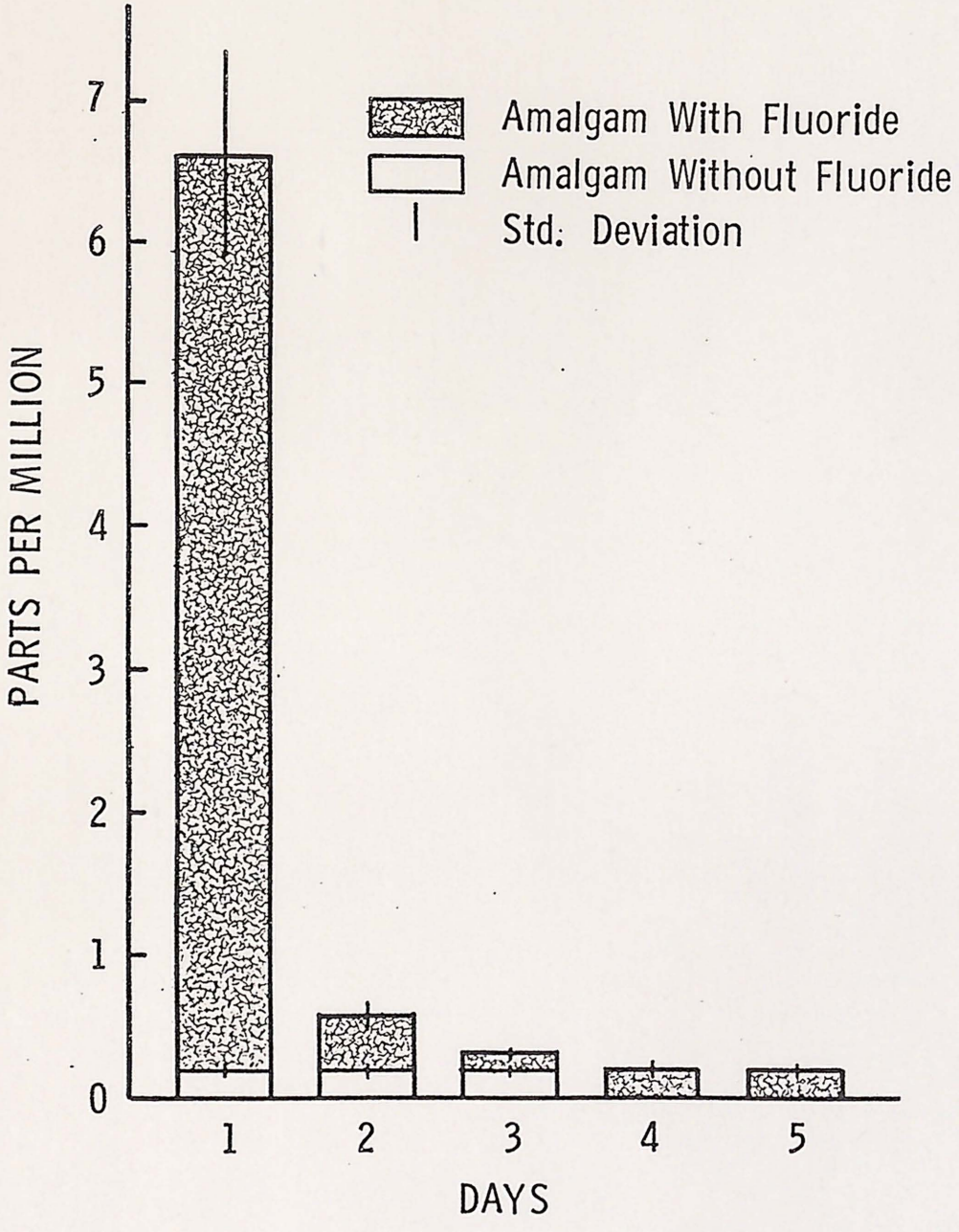


Figure 5. Percent change in the fluoride content of intact enamel surface after contact with the test and control amalgams for the time intervals evaluated.

AVERAGE FLUORIDE UPTAKE

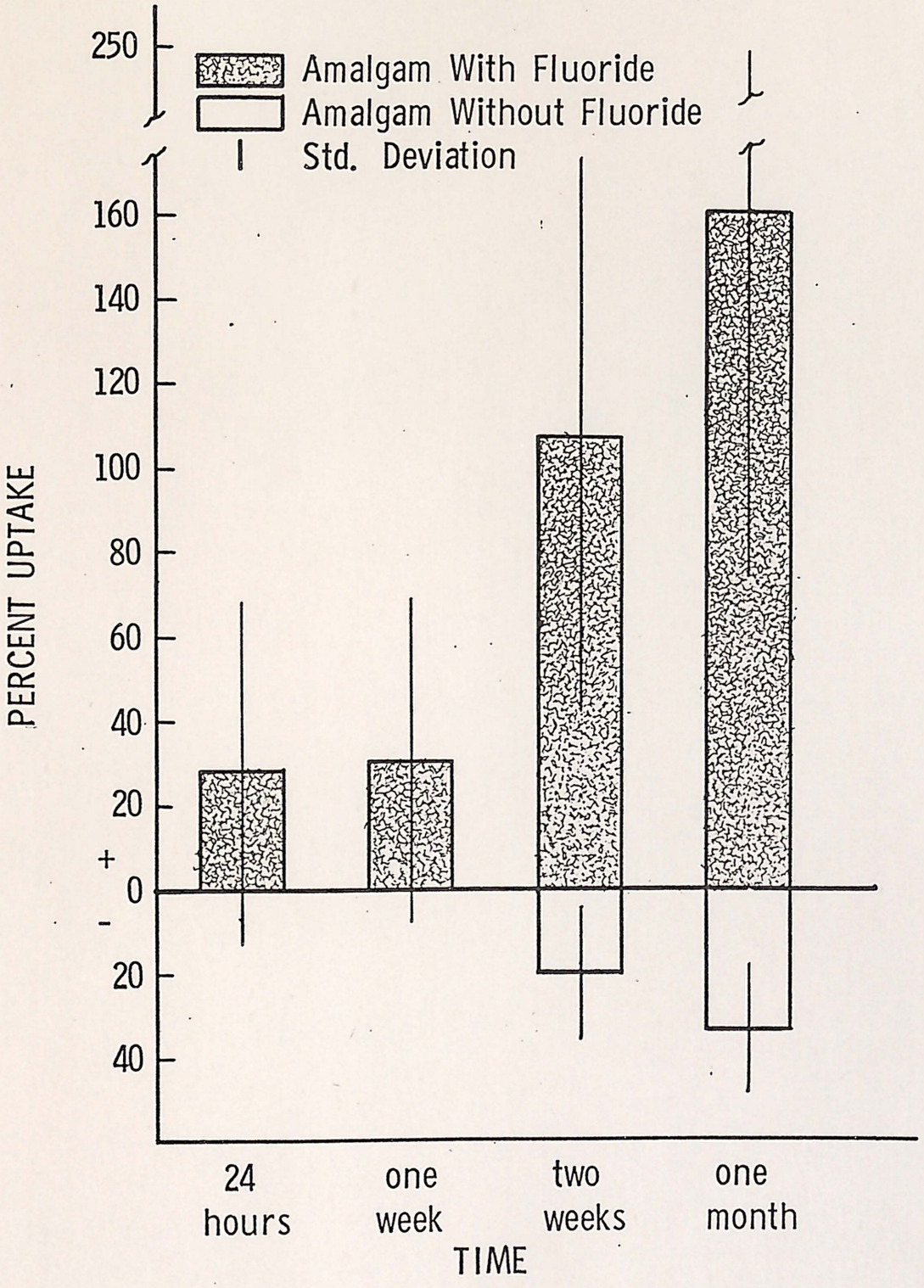


Figure 6. Percent change in the enamel solubility of intact enamel surface after contact with the test and control amalgams for the time intervals evaluated.

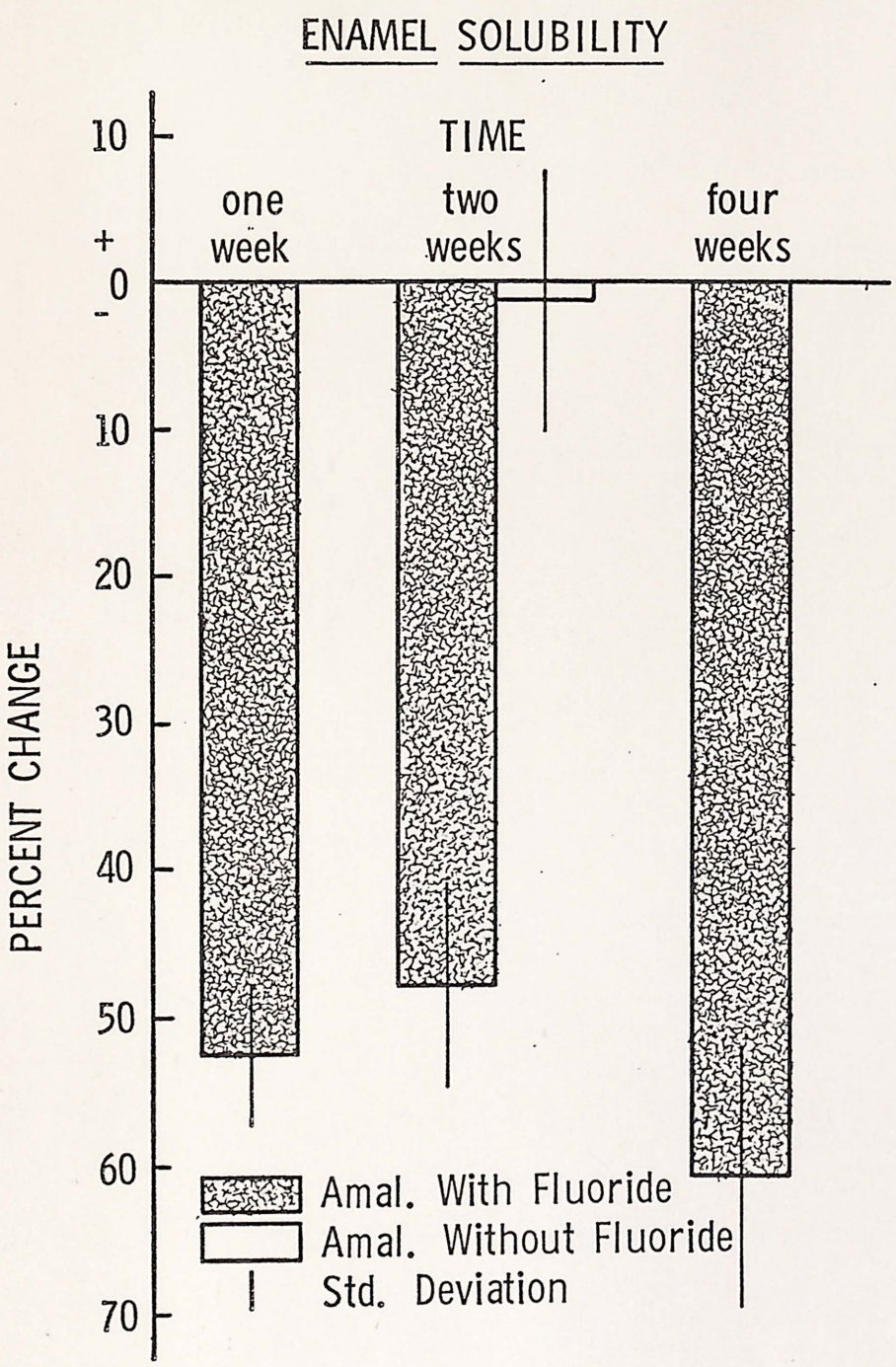

ENAMEL SOLUBILITY
TIME
one week
two weeks
four weeks
+
0
-
10
10
20
30
40
50
60
70
PERCENT CHANGE
Amal. With Fluoride
Amal. Without Fluoride
Std. Deviation

Figure 7. Comparison of the compressive strengths of the test and control amalgams at the time intervals evaluated.

AVERAGE COMPRESSIVE STRENGTH

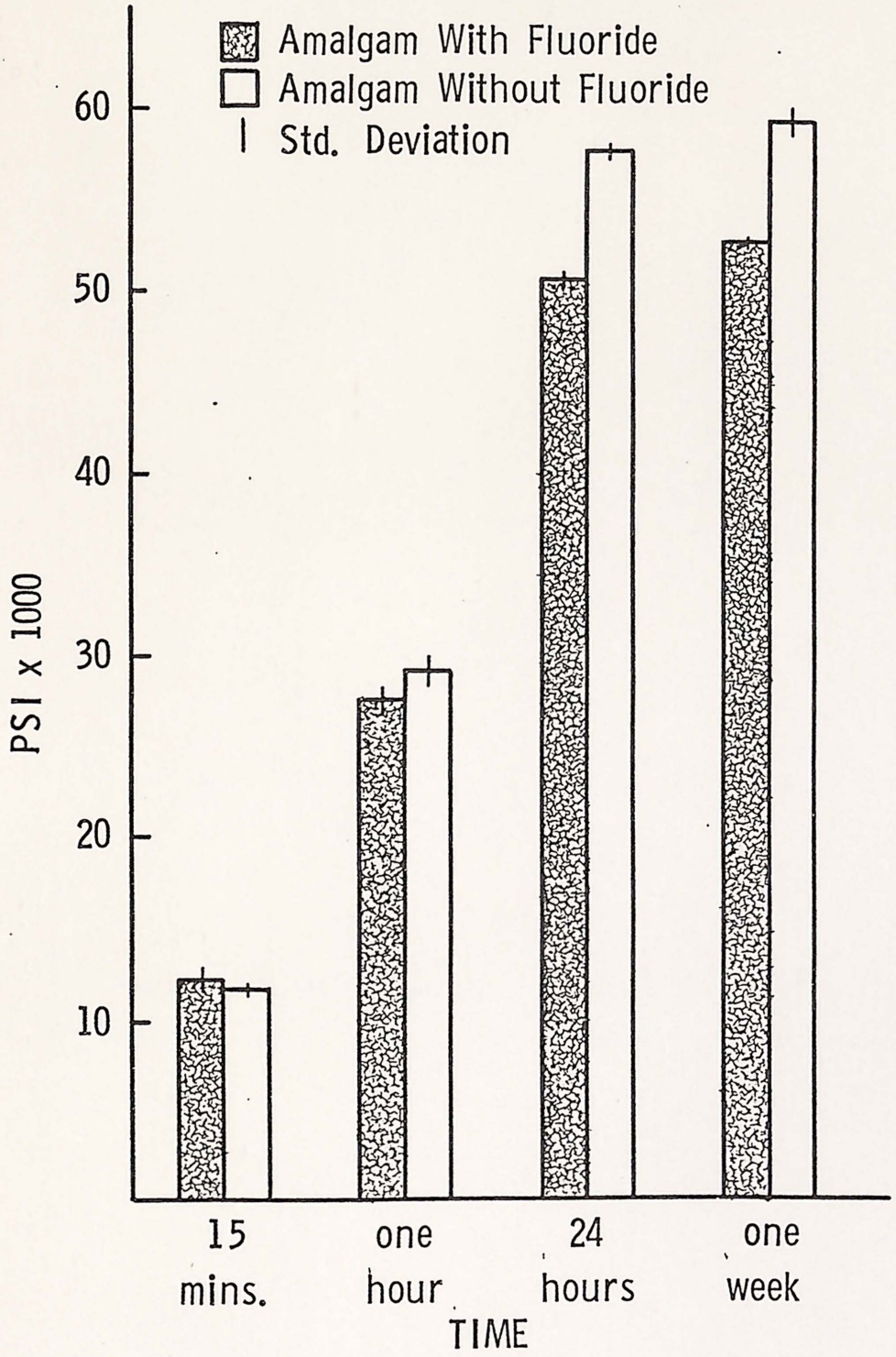


Figure 8. Comparison of the tensile strengths of the test and control amalgams at the time intervals evaluated.

AVERAGE TENSILE STRENGTH

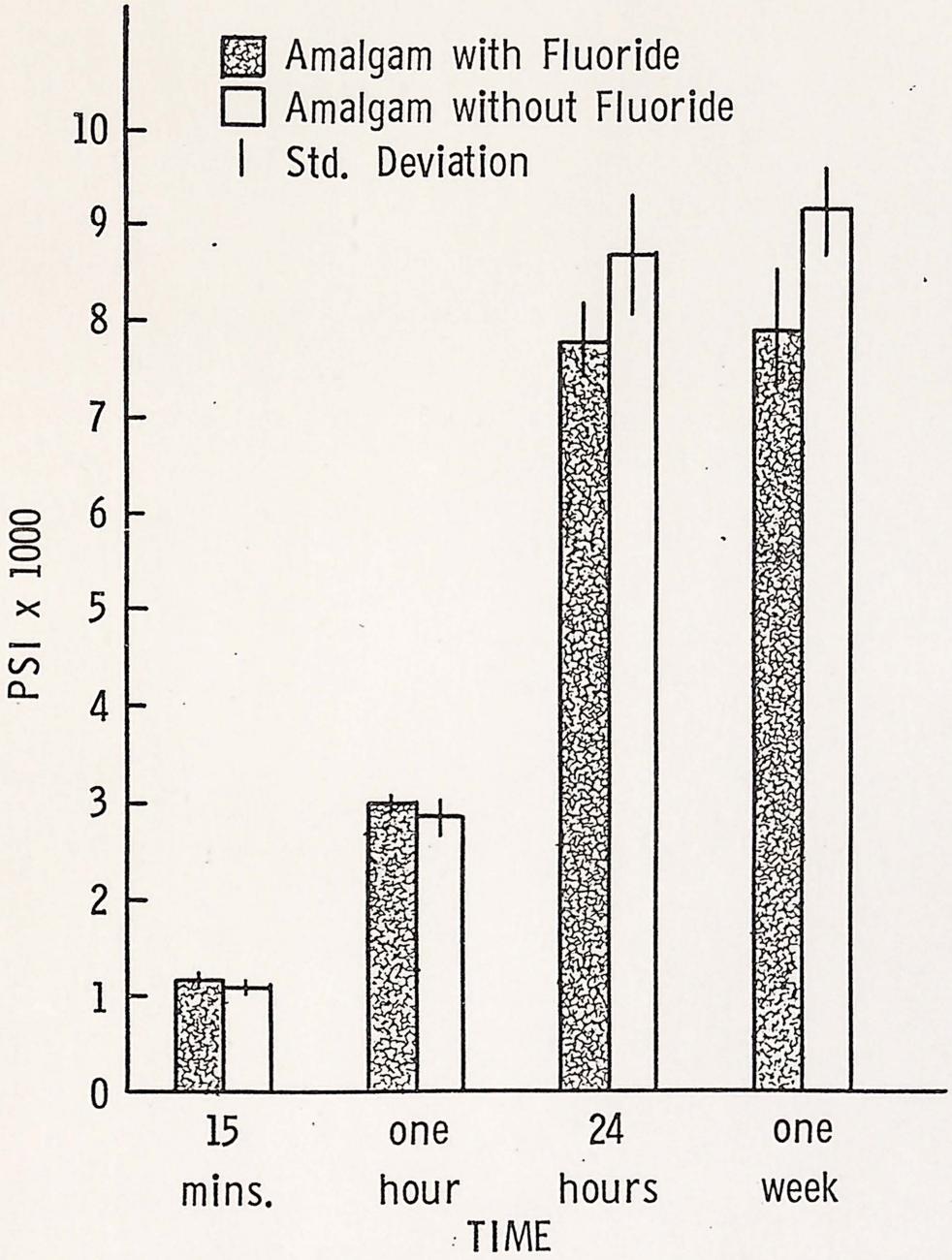


Figure 9. Comparison of the Knoop hardness of the test and control amalgams at the time intervals evaluated.

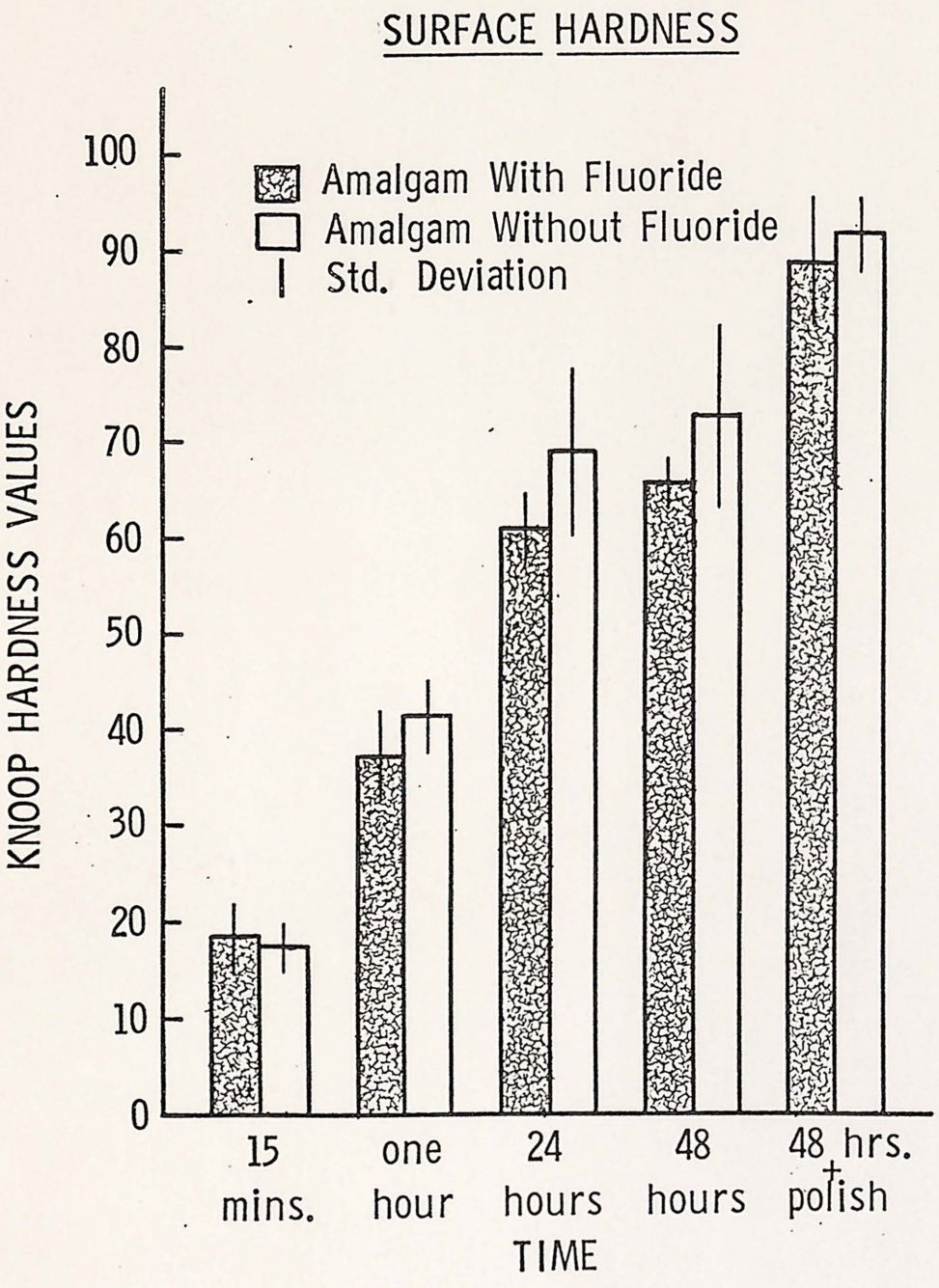

SURFACE HARDNESS
KNOOP HARDNESS VALUES
100
90
80
70
60
50
40
30
20
10
0
Amalgam With Fluoride
Amalgam Without Fluoride
Std. Deviation
15 mins.
one hour
24 hours
48 hours
48 hrs. polish
TIME

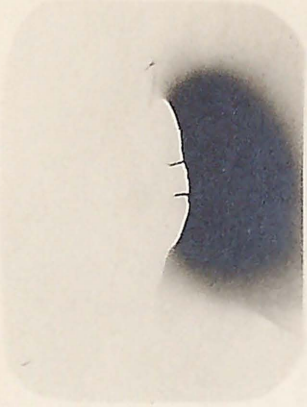
Figure 10. Representative autoradiographs illustrating the leakage patterns of restorations stored in water for one week.

Figure 11. Representative autoradiographs illustrating the leakage patterns of restorations subjected to thermocycling.

STORAGE IN WATER
One Week

Restorations with Fluoride

Restorations without Fluoride



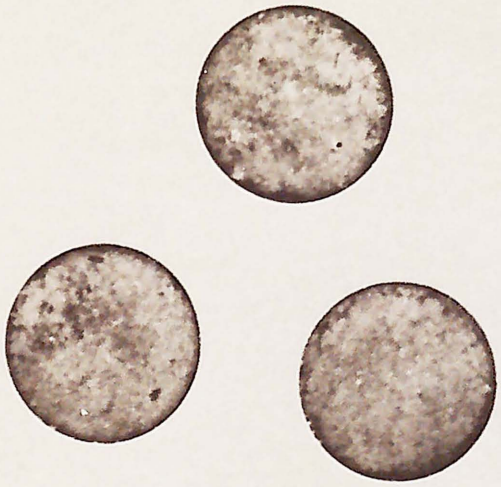
THERMOCYCLED IN WATER
One Week
(2500 cycles, 60^{0} F gradient)

Restorations with Fluoride

Restorations without Fluoride

Figure 12. Representative specimens of the fluoride containing amalgam illustrating tarnish and corrosion after two weeks of exposure to a 0.05 percent solution of sodium sulfide.

Figure 13. Representative specimens of the fluoride free amalgam illustrating tarnish and corrosion after two weeks of exposure to a 0.05 percent solution of sodium sulfide.



DISCUSSION

Part I: Laboratory Phase

Fluoride Release, Fluoride Uptake, Enamel Solubility

The laboratory data indicate that fluoride is released from amalgam containing stannous hexafluorozirconate, and that the fluoride content and solubility of enamel is significantly altered when exposed to amalgam containing this fluoride compound at 0.5% by weight. The release of the fluoride occurred primarily during the first 24 hours, and diminished rapidly thereafter. This release pattern is similar to other restorative materials that contain fluoride.[3,92] Comparing the five-day fluoride release from amalgam with a five-day release from a silicate cement,[a] the amalgam released only about one-third as much fluoride.[105] Also, the release from amalgam was essentially zero by the fourth day, whereas the release from the silicate cement continued at a low rate during the fourth and fifth days. A recent study by DeFreitas[106] has shown that there was a sustained fluoride release from silicate cement which occurred at a constant rate over a test period of one year. It may be this long-term release of fluoride that provides the resistance to recurrent caries about silicate restorations.

The quantity of fluoride released from the amalgam and that would be available to adjacent tooth tissues was small. Still there was a 161 percent increase in the fluoride content of enamel exposed to the fluoride-containing amalgam for one month. For comparison, silicate cement was found in two studies to increase enamel fluoride content 239 and 296 percent respectively.[92, 105] The fluoride-free control amalgam

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[a] MQ Silicate Cement, S.S. White

caused a reduction in the fluoride content of the enamel, as has been reported for other non-fluoride-containing materials.[3,92]

In this study stannous hexafluorozirconate reduced enamel solubility 61 percent over a one-month period. Phillips and Swartz have reported that silicate cement reduces enamel solubility in the area of 25 percent.[2] The presence of the stannous and the zirconium ions undoubtedly must aid in the effect of the fluoride compound. This could explain some of the observed differences.

For additional comparisons, it is difficult to correlate the results of other enamel solubility studies because different decalcifying solutions, pH levels, fluoride concentrations and application times are involved. Still some generalizations can be made. Solutions of stannous fluoride, at concentrations of 0.5 to 10 percent and in contact with intact enamel for two to four minutes, can reduce enamel solubility about 75 percent.[17,18,107] Stannous hexafluorozirconate at concentrations of 1.0 to 20.6 percent and applied from two to four minutes can reduce enamel solubility about 85 percent.[17,18] Muhler simulated the clinical application of a two percent stannous fluoride topical and reduced enamel solubility 39 percent.[108] Though the data are very limited, the 30 percent stannous fluoride used as a cavity liner beneath amalgam and evaluated at 24 hours reduced the solubility of enamel adjacent to the amalgam 61 percent.[105] Again, no direct comparison can be made, but it appears that adding stannous hexafluorozirconate to amalgam at 0.5% by weight can reduce enamel solubility similarly to that produced by the topical application of various fluorides.

Summarizing from these fluoride data, it can be assumed that, clinically, as fluids penetrate the tooth-amalgam interface, fluoride could be released, taken up by surrounding tooth tissues, making them less susceptible to recurrent caries. The reaction would occur fairly rapidly and have an effectiveness similar to a topical application of fluoride. The advantage of incorporating the fluoride into the amalgam would be the elimination of the topical application procedure to the cavity preparation.

Still to be considered is the fact that the fluoride release and reaction is of a relatively short duration for the dental amalgam; and though the initial protection of reduced enamel solubility appears to be greater than that afforded by silicate cement, the fluoride release, and therefore the reaction, is continuous for silicate cement. Again, it may be this continuous availability of fluoride that provides silicate restorations their protection from recurrent caries.

Physical Properties of the Test Amalgam

The results of the tests evaluating the effect stannous hexafluorozirconate at 0.5% by weight has on the physical properties of amalgam indicate that this amalgam meets the acceptance requirements of the ADA specification #1 for alloy for dental amalgam. The 15-minute diametral tensile strength of 1154 psi was well above the 290 psi specification, and shows that the alloy has a relatively fast rate of hardening and early strength. This was also apparent from the 15-minute and one-hour compressive strength data. Though statistically the fluoride compound did significantly reduce the one-week tensile strength and the 24-hour and one-week compressive strength, the overall

strength characteristics of the fluoride-containing amalgam were very acceptable as related to the tensile and compressive strengths considered necessary for dental amalgam. These findings are similar to results reported in other fluoride amalgam studies.[10-15]

The 21-hour flow properties and the dimensional setting change properties as described in the specification #1 were adequately met by the fluoride-containing amalgam. In fact, the stannous hexafluorozirconate at 0.5% by weight had essentially no altering effect on these properties. Also surface hardness appeared not to be affected by the addition of the fluoride compound.

Two properties of the amalgam were significantly altered by the 0.5% stannous hexafluorozirconate. They were marginal leakage and resistance to tarnish and corrosion.

The marginal leakage pattern of the fluoride-containing amalgam was less severe than the fluoride-free amalgam, though the depth of leakage was the same. This could be accounted for by the rapid formation of corrosion products or precipitates that reduced the space along the tooth-material interface during the seven day's storage in water and thermocycling. The presence of calcium ions could precipitate fluoride; but if the Ca^{45} radioisotope used to evaluate leakage precipitated fluoride and occluded the interface space, the calcium fluoride precipitate would still have been radioactive, and the severity of the marginal leakage still depicted on the autoradiographs.

The behavior of the fluoride-containing amalgam during the test for resistance to tarnish and corrosion gives support to corrosion products causing the rapid reduction of the interface space and marginal leakage. Throughout the two-week alternating exposure to air and the 0.05 percent sodium sulfide solution, the fluoride-containing amalgam showed a continuing severity of corrosion associated with the margins of the amalgam specimens.

Extensive attempts were made to analyze known fluoride concentrations in amalgam in an effort to determine possible fluoride distribution and concentration in various areas of an amalgam specimen. Unfortunately none of the tests were capable of or reliable in determining fluoride concentrations in amalgam. But based on the corrosion pattern of specimens subjected to the sulfide solution, it can be theorized that there was an apparent tendency for the fluoride compound to be worked or carried by mercury to the periphery of the amalgam specimens during condensation. Then the fluoride compound at the surface of the amalgam was leached out and/or broken down chemically, as a reaction of stannous ions with sulfide ions and a formation of a precipitate of stannous sulfide. The resulting microscopic pitting would leave an increased surface area susceptible to the direct chemical attack by the sulfide solution.

It may be advantageous to have the fluoride compound carried to the margins of the amalgam, releasing a greater amount of fluoride to adjacent tooth tissues. Also once the fluoride release and reaction with tooth tissues has occurred, a rapid filling of the interface space would be beneficial since no cavity liner is used with fluoride-

containing amalgam to obtain an initial seal against marginal leakage. However, any advantages would be eliminated if clinically the higher concentration of the fluoride compound near the margins caused an excessive marginal deterioration due to corrosion and reduced strength.

Part II: Clinical Phase

A discussion of the clinical results must begin with emphasizing that the study involves only one-year data and may not be indicative of what will be seen with the proposed long-term recall evaluations. With that in mind, the clinical phase of the study indicated that, at one year, the addition of stannous hexafluorozirconate to a spherical dental alloy at 0.5% by weight had no deleterious effect on the clinical performance of the amalgam. The breakdown in the marginal adaptation of the test and control amalgams was, in general, characteristic of well-placed amalgam restorations. The same was true for the surface changes that occurred.

Based on the laboratory observations of the reduced resistance to corrosion by the fluoride-containing amalgam, it had been anticipated that there might be a difference in the clinical performance of the test amalgam, manifest as a more severe marginal and surface deterioration. This noncorrelation between observed laboratory and clinical findings can be theorized to be due to the different corrosion reactions occurring in the laboratory and clinical environments. The surface leaching of the fluoride and the resulting microscopic pitting may be the same for both, but, in the laboratory test, the corrosion reaction was a direct chemical attack and union of the metallic and nonmetallic elements. Chemical corrosion plays a lesser role in the mouth where the corrosion reaction is primarily an electrolytic process.

Attempting to correlate a laboratory electrolytic corrosion test with oral findings would also be difficult, because there are various types of electrolytic

corrosions, generally occurring simultaneously in the restoration. In addition, the oral environment is not constant. Saliva characteristics, pH values, stress and hygiene habits continually fluctuate. Therefore chemical and electrolytic corrosion laboratory tests remain as screening tests that may indicate potential problems. But for the moment the addition of stannous hexafluorozirconate to amalgam appears to create no corrosion problems clinically.

There were no fractured amalgams in this study and, again, marginal breakdown was similar for both the test and control amalgams. Yet the laboratory strength properties were lower for the fluoride-containing amalgam. Compressive and tensile tests are accepted as reliable tests to predict resistance to functional stresses. However, the clinical significance of varying strength properties has not been adequately determined. Gross fractures of amalgam restorations appear to be more closely associated with traumatic occlusion than amalgam strength.[30] Also strength properties alone do not adequately account for marginal breakdown. Hardness, ductility, resilience and flow must be considered in any quantitative evaluation.

In this case, though reduced, the compressive and tensile strengths of the test amalgam were well within the ranges considered necessary to resist functional stresses; and the significant strength differences observed in the laboratory appear to have no discernable clinical significance.

Clinical studies are necessary to evaluate and correlate the performance of restorative materials. But it may not be an efficient way to evaluate the affect a material may have on recurrent caries. A review of the clinical studies performed

and supported over a six-year period by the former Materials and Technology Branch, Division of Dental Health, National Institutes of Health, indicates that recurrent caries has been an insignificant finding in well controlled studies.[109] Recurrent caries was not observed for any of the test and control amalgams in this study.

A dentist who knows that his restorations are going to be annually evaluated by independent, trained examiners is undoubtedly more meticulous in preparing the teeth and manipulating the materials. This in itself increases resistance to recurrent caries. Also it is difficult to find a stable population which could be considered more susceptible to recurrent caries no matter how ideal the restorations. Therefore, to evaluate the anticariogenic properties of a material, in vitro artificial caries or animal studies may be a more efficient method. Still, whatever the results, it must be realized that the prevention of recurrent caries begins with appropriate cavity design, care in manipulating materials, and patient responsibility in diet and oral hygiene. The reduced enamel solubility resulting from the fluoride additive, as evidenced in the laboratory, is only a potential adjunct in the prevention of recurrent caries. It cannot excuse a less conscientious operative procedure.

SUMMARY AND CONCLUSIONS

A study was conducted to evaluate the laboratory properties and the clinical performance of a spherical dental amalgam alloy containing stannous hexafluorozirconate at 0.5% by weight. For comparison, the same alloy free of fluoride served as a control.

The laboratory results indicated that fluoride was released from the fluoride-containing amalgam, that there was an enamel uptake of the fluoride, and that the solubility of enamel was reduced to a degree similar to that produced by the topical application of various fluorides.

The ADA specifications for dental amalgam were met by the fluoride-containing spherical alloy. Though the compressive and tensile strengths of the amalgam were reduced by the addition of the fluoride compound, the strengths were still well above what is considered necessary for an amalgam.

The fluoride-containing amalgam was more susceptible to a direct chemical corrosion reaction, particularly at the margins of the specimens. This increase in corrosion at the margins could explain the observed change in the marginal leakage pattern of the fluoride-containing amalgam. Its leakage pattern was less severe than that for the control amalgam.

The clinical results of the test and control restorations were reported for only one year. This should be kept in mind, for differences may occur at the future evaluation periods. But at one year, there appeared to be no correlation between the differences observed in the laboratory and the clinical performance of the test and control amalgams. There was no significant difference in the marginal adaptation

of the two amalgams or in their surface characteristics. Also, no recurrent caries was associated with any of the test or control restorations.

In conclusion, the spherical dental amalgam alloy containing stannous hexafluorozirconate at 0.5% by weight meets ADA specification #1 for alloys for dental amalgams. The addition of the fluoride compound has no deleterious affect on the clinical performance of the amalgam. The reduced enamel solubility resulting from the fluoride additive is a potential adjunct in the prevention of recurrent caries. The advantage of incorporating the fluoride into the amalgam would be the elimination of the topical fluoride application procedure to the cavity preparation. Still, the prevention of recurrent caries must begin with appropriate cavity design, care in manipulating materials, and patient or parent responsibility in diet and hygiene practices.

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ABSTRACT

EVALUATION OF A DENTAL AMALGAM ALLOY CONTAINING THE FLUORIDE ADDITIVE STANNOUS HEXAFLUOROZIRCONATE

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This study was designed to evaluate a dental alloy containing stannous hexafluorozirconate at 0.5 percent by weight, to determine how the fluoride additive might affect the physical properties of the alloy and the clinical performance of the amalgam restorations.

Using established methodology, the fluoride containing alloy was evaluated in the laboratory for fluoride release, enamel uptake and solubility, strength, hardness, flow, dimensional change, corrosion resistance, and marginal leakage. Clinically, 98 pairs of test and control restorations were placed and evaluated for marginal adaptation, surface characteristics, and recurrent caries.

The results indicate that the fluoride containing alloy meets the ADA specifications for amalgam alloys, though the strength properties of the amalgam are reduced. The increased susceptibility to corrosion noted in the laboratory for the fluoride-containing amalgam did not correlate with the clinical performance of the restorations, which showed no deleterious affects resulting from the addition of the fluoride compound. The reduced enamel solubility observed in the laboratory can be considered an adjunct in the prevention of recurrent caries, though no recurrent caries was reported for either the test or control restorations. Again, the prevention of recurrent caries must begin with appropriate cavity design, care in manipulation of materials and responsible diet and hygiene practices.